CURRENT REGULATION	PROPOSED CHANGES	RATIONALE FOR CHANGE
130.600: Scope and Purpose of Maternal and Newborn Services	~~130.600: Scope and Purpose of Maternal and Newborn Services~~	
105 CMR 130.600 through 130.650 (Maternal and Newborn Care) are designed both to reflect the evolving trends in the maternal-newborn specialty area and to better ensure quality health care for the Commonwealth's mothers and newborns. 105 CMR 130.600 through 130.650 represent the collaborative efforts of the Division of Health Care Quality and the Bureau of Parent, Child and Adolescent Health, with consultation from the Division of Communicable Diseases and an advisory committee composed of experts from all relevant disciplines and consumer representatives.	~~105 CMR 130.600 through 130.650 (Maternal and Newborn Care) are designed both to reflect the evolving trends in the maternal-newborn specialty area and to better ensure quality health care for the Commonwealth's mothers and newborns. 105 CMR 130.600 through 130.650 represent the collaborative efforts of the Division of Health Care Quality and the Bureau of Parent, Child and Adolescent Health, with consultation from the Division of Communicable Diseases and an advisory committee composed of experts from all relevant disciplines and consumer representatives.~~	**The entire section 130.600, outlining the scope and purpose of the regulations, is eliminated here. Only the regulatory requirements are now included in this proposed regulation revision document.**
Since the 1960's two major trends dominated the field of maternal-newborn care. First, the consumer movement focused increased attention on birth as a normal process and the value of family participation in that process. Second, this trend was paralleled by the rapid growth of knowledge and skills in the neonatal specialty field resulting in highly technological services for sick newborns.	~~Since the 1960's two major trends dominated the field of maternal-newborn care. First, the consumer movement focused increased attention on birth as a normal process and the value of family participation in that process. Second, this trend was paralleled by the rapid growth of knowledge and skills in the neonatal specialty field resulting in highly technological services for sick newborns.~~	
105 CMR 130.600 through 130.650 are based on the recommendations of the American Academy of Pediatrics and the American College of Obstetrics and Gynecology which recognize these trends. These recommendations, outlined in the 1988 *Guidelines for Perinatal Care*, emphasize that a comprehensive systems approach to the delivery of maternal-newborn care is required to reduce infant morbidity and mortality. The system defines three levels of care, ranging from the care of low-risk to high-risk mothers and newborns. Each level and the services it provides is designed to meet the needs of specific maternal-newborn patients based on their risk assessment. In addition to the levels, key elements of the system include close clinical collaboration between facilities and the sharing of professional educational offerings.	~~105 CMR 130.600 through 130.650 are based on the recommendations of the American Academy of Pediatrics and the American College of Obstetrics and Gynecology which recognize these trends. These recommendations, outlined in the 1988 *Guidelines for Perinatal Care*, emphasize that a comprehensive systems approach to the delivery of maternal-newborn care is required to reduce infant morbidity and mortality. The system defines three levels of care, ranging from the care of low-risk to high-risk mothers and newborns. Each level and the services it provides is designed to meet the needs of specific maternal-newborn patients based on their risk assessment. In addition to the levels, key elements of the system include close clinical collaboration between facilities and the sharing of professional educational offerings.~~	.
105 CMR 130.600 through 130.650 follow the principles described in the national recommendations with modifications to meet the needs of the Commonwealth's health care delivery system which is relatively resource rich compared to many states. 105 CMR 130.600 through 130.650 are designed to recognize the current maternal-newborn care system while providing for the system's dynamic evolution as advances in perinatal medicine occur. 105 CMR 130.600 through 130.650 establish three levels of care:	~~105 CMR 130.600 through 130.650 follow the principles described in the national recommendations with modifications to meet the needs of the Commonwealth's health care delivery system which is relatively resource rich compared to many states. 105 CMR 130.600 through 130.650 are designed to recognize the current maternal-newborn care system while providing for the system's dynamic evolution as advances in perinatal medicine occur. 105 CMR 130.600 through 130.650 establish three levels of care:~~	

CURRENT REGULATION	PROPOSED CHANGES	RATIONALE FOR CHANGE
* Level I: Community-Based Maternal-Newborn Service including a Level IB Service with a Continuing Care Nursery	~~* Level I: Community-Based Maternal-Newborn Service including a Level IB Service with a Continuing Care Nursery~~	
* Level II: Community-Based Maternal-Newborn Service with a Special Care Nursery	~~* Level II: Community-Based Maternal-Newborn Service with a Special Care Nursery~~	
* Level III: Perinatal Center and/or Neonatal Intensive Care Unit	~~* Level III: Perinatal Center and/or Neonatal Intensive Care Unit~~	
Included in Level I care are provisions for a Level IB continuing care nursery service. These nurseries represent a transitional stage to Level II Special Care Nurseries for a small group of services caring for certain categories of mild to moderately ill newborns born within that hospital or for retrotransferred infants. In contrast, the Level II Special Care Nursery is part of a larger system of care, providing more specialized services to sicker infants born within the hospital or transferred from level I or IB services. These infants do not require the comprehensive range of services offered by the Level III unit but do require close, ongoing medical assessment and management and/or prolonged hospitalization.	~~Included in Level I care are provisions for a Level IB continuing care nursery service. These nurseries represent a transitional stage to Level II Special Care Nurseries for a small group of services caring for certain categories of mild to moderately ill newborns born within that hospital or for retrotransferred infants. In contrast, the Level II Special Care Nursery is part of a larger system of care, providing more specialized services to sicker infants born within the hospital or transferred from level I or IB services. These infants do not require the comprehensive range of services offered by the Level III unit but do require close, ongoing medical assessment and management and/or prolonged hospitalization.~~	
The decision to admit or transfer a mother and/or newborn to a particular level of care rests with the professionals who determine the degree of risk for poor pregnancy outcome. However, the integrity of the family unit should also be maintained whenever possible. Therefore, guiding principles for patient placement include:	~~The decision to admit or transfer a mother and/or newborn to a particular level of care rests with the professionals who determine the degree of risk for poor pregnancy outcome. However, the integrity of the family unit should also be maintained whenever possible. Therefore, guiding principles for patient placement include:~~	
* The mother should be transferred prior to the birth to the service level warranted by her condition or the anticipated condition of her infant.	~~* The mother should be transferred prior to the birth to the service level warranted by her condition or the anticipated condition of her infant.~~	
* When the infant's care requires separation from the mother, provisions should be made to promote maternal, infant and family contact.	~~* When the infant's care requires separation from the mother, provisions should be made to promote maternal, infant and family contact.~~	
* When clinically safe to do so, the previously transferred infant should be moved back to an available community facility providing the facility level of care required and within a geographic location convenient to the family.	~~* When clinically safe to do so, the previously transferred infant should be moved back to an available community facility providing the facility level of care required and within a geographic location convenient to the family.~~	
105 CMR 130.600 through 130.650 are also designed to promote the concept of family centered care within the specific facility's maternal-newborn service. Recognition is given to emerging practices which support this concept. For example, 105 CMR 130.600 through 130.650 recognize single-room maternity care in which the mother labors, delivers, recovers and remains until discharge in a single-room with her infant and family.	~~105 CMR 130.600 through 130.650 are also designed to promote the concept of family centered care within the specific facility's maternal-newborn service. Recognition is given to emerging practices which support this concept. For example, 105 CMR 130.600 through 130.650 recognize single-room maternity care in which the mother labors, delivers, recovers and remains until discharge in a single-room with her infant and family.~~	

CURRENT REGULATION	PROPOSED CHANGES	RATIONALE FOR CHANGE
Because there are certain basic requirements for all maternal-newborn services despite the level, 105 CMR 130.600 through 130.650 are organized into two sections, one for general requirements (105 CMR 130.615 through 130.628) and the other for level-specific requirements (105 CMR 130.630 through 130.650). Each service must comply with the provisions of 105 CMR 130.615 through 130.628 (General Requirements) as well as those applicable to its specific designated level.	~~Because there are certain basic requirements for all maternal-newborn services despite the level, 105 CMR 130.600 through 130.650 are organized into two sections, one for general requirements (105 CMR 130.615 through 130.628) and the other for level-specific requirements (105 CMR 130.630 through 130.650). Each service must comply with the provisions of 105 CMR 130.615 through 130.628 (General Requirements) as well as those applicable to its specific designated level.~~	
Finally, the Department recognizes the continuing evolution of mother and newborn care and plans to convene a multidisciplinary Perinatal Advisory Committee to advise the Department on ongoing issues related to the licensure of hospital maternal-newborn services.	~~Finally, the Department recognizes the continuing evolution of mother and newborn care and plans to convene a multidisciplinary Perinatal Advisory Committee to advise the Department on ongoing issues related to the licensure of hospital maternal-newborn services.~~	.
130.601: Definitions		
The following definitions apply in 105 CMR 130.000 when used with regard to maternal-newborn services:		
	Antepartum Patient shall mean any pregnant woman greater than 19 weeks gestation who is characterized as having a high-risk obstetric complication or a patient who is pregnant with a medical or surgical condition. Birthing Room shall mean a room designed to provide family-centered care in a "homelike" environment for low-risk mothers throughout the labor, delivery and immediate recovery periods~~. Local and pudendal anesthesia only shall be administered in a birthing room~~. **Certified Nurse Midwife shall mean an individual authorized by the Board of Registration in Nursing under M.G.L.c.112, 80C and authorized to practice as a nurse-midwife pursuant to 244 CMR 4.00 et seq.** **Cesarean** /Delivery~~/Cesarean Birth~~ Room shall mean a room staffed and equipped to handle low-risk to high-risk deliveries, including cesarean	New definitions noted in bold type in this section are added for clarity. The restrictions in type of anesthesia is no longer needed, because proposed change to regulations below regarding birthing rooms requires that 'birthing room' facilities meet all the requirements of a labor and delivery room. The name of the room type is changed to be consistent with the most current version of the Guidelines for Design Construction of Hospital

CURRENT REGULATION	PROPOSED CHANGES	RATIONALE FOR CHANGE
	births, and have capabilities of administering all forms of anesthesia, including inhalation agents. **Clinical Nurse Specialist shall mean a registered nurse with a current license from the Massachusetts Board of Registration in Nursing. For the purpose of these regulations, the clinical nurse specialist must be masters prepared with clinical expertise in advanced nursing practice in the specialty area of maternal or neonatal health.** **Critical Care Obstetrics Team shall mean a team including representatives from the following available 24 hours a day, 7 days a week: Maternal-fetal medicine consultant; in-house obstetrician; in-house nursing staff with demonstrated competency in critical care; in-house anesthesia; in-house neonatologist and other medical specialties available, as needed, including at a minimum infectious disease, pulmonary, surgery, cardiology.** Continuing Care Nursery shall mean a nursery that is specially equipped and staffed to offer a variety of specialized services as specified in 105 CMR 130.630(E) to mild or moderately ill infants born at the level IB hospital or to retrotransferred stable-growing or recovery infants who do not require intensive or special care. Designated service levels shall mean ~~the following~~ levels of care based on services provided by the hospital. ~~The designated level of care for each maternal-newborn service shall be~~ as approved by the Department of Public Health. Family-centered Care shall mean a method of providing services, which fosters the establishment and maintenance of parent-newborn-family relationships. The family may consist of the father, mother and child and/or include other identified support persons (biologically or non-biologically related) for the mother and infant.	and Healthcare Facilities published by the Department of Health and Human Services and American Institute of Architects.

CURRENT REGULATION	PROPOSED CHANGES	RATIONALE FOR CHANGE
	Family Practitioner shall mean a physician licensed by the Massachusetts Board of Registration in Medicine who has completed a residency in family medicine, which includes training in internal medicine, pediatrics and obstetrics and is certified or an active candidate for certification by the American Board of Family Practice. **Freestanding Pediatric Hospital with Neonatal Subspecialty Services shall mean a service that has the capabilities to provide care to the moderately to severely ill neonate: infants who require neonatal intensive care services and provides newborn care to patients with actual medical problems.** Gynecology Patient shall mean any woman with or suspected of having a health problem related to her reproductive organs. Labor Room shall mean an area in which the mother experiences the first stage of labor. Labor-Delivery Suite shall mean that part of a maternal and newborn service used to care for patients during labor, delivery and recovery. It shall include physically contiguous labor room(s), **cesarean/delivery** ~~delivery/cesarean birth~~ room(s) and ancillary facilities. Labor-Delivery-Recovery Room shall mean a room designed, staffed and equipped to care for mothers, newborns and their families throughout the labor, delivery and recovery periods. Anesthesia use shall be limited to the local and regional modes Labor-Delivery-Recovery-Postpartum Room (Single-Room Maternity Care) shall mean a room designed, staffed and equipped to care for mothers, newborns and their families throughout the labor, delivery, recovery and postpartum periods. Anesthesia use shall be limited to the local and regional modes. **Lactation Consultant shall mean an individual certified by International Board Certified Lactation Consultant (IBCLC) or an individual with**	For clarity, the phrase ‘facility with a Level III pediatric service’ is replaced by ‘ Freestanding Pediatric Hospital with Neonatal Subspecialty Services’.

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	equivalent training and experience. Level I - Community-Based Maternal-Newborn Service **shall mean a community –based maternal and newborn service including Level I A and Level I B services that meets the requirements in 130.630.** **Level I A Service** shall mean a service community-based maternal and newborn service that provides ~~care to routine maternal patients as well as those with actual or potential problems, the management of which are medically assessed as being within the capabilities of the Level I facility. A Level I service cares for infants born at that hospital who do not need the specialized services of a Level II or III service as defined in 105 CMR 130.601(A) and for retrotransferred stable - growing or recovery infants.~~ **for the care and management of maternal conditions consistent with ACOG guidelines, including management of pregnancies judged unlikely to deliver before 35 weeks gestation.** **Level I B Service shall mean a Level I community-based maternal and newborn service with a continuing care nursery that provides for the care and management of maternal conditions consistent with ACOG guidelines, including management of pregnancies judged unlikely to deliver before 35 weeks gestation.** Level II Service s**hall mean a community-based maternal and newborn service with** a Special Care Nursery **including Level II A and Level II B services.**~~shall mean a service that provides care for routine maternal and newborn patients, as well as for the majority of patients with potential and actual problems. A level II unit provides service both to infants born at the Level II hospital and to mothers and infants transferred in from Level I and Level IB services.~~ **that meets the requirements in 130.640.** **Level II A Service shall mean a community-based Level II maternal and newborn service with a Special Care Nursery that provides for the care and management of maternal conditions consistent with ACOG**	Definition maintains current recognition of two level of Level I community service. The amended language clarifies this by specifying the two levels as Level I A and Level I B. The levels of maternal and newborn care are updated to reflect the definitions and distinctions outlined by the American Academy of Pediatrics. For clarity in these regulations, the proposed definitions are made more specific by further describing the level of obstetrical care and gestational age. Gestational age is an indicator of the anticipated staff, services and facilities required for safe care.

CURRENT REGULATION	PROPOSED CHANGES	RATIONALE FOR CHANGE
	guidelines, including management of pregnancies judged unlikely to deliver before 34 weeks gestation. **Level II B Service shall mean a community-based maternal-newborn service with a Special Care Nursery that provides for the care and management of maternal conditions consistent with ACOG guidelines, including management of pregnancies judged unlikely to deliver before 32 weeks gestation. The Level II B service meets the requirements in 130.640 (C)** Level III - ~~Perinatal Center and/or Neonatal Intensive Care Unit~~ Maternal and Newborn Service ~~Perinatal Center shall mean a hospital service that provides care and services to mothers and newborns of all risk assessment levels, including those with unusual/severe complications or anomalies. The Perinatal Center shall offer a comprehensive range of specialty and subspecialty services to maternal and newborn patients from the center or referred from Level I II services. The Perinatal Center shall be located in a hospital which has capabilities to manage the maternal patient requiring intensive care. The Perinatal Center shall maintain a Neonatal Intensive Care Unit~~ **shall mean a maternal and newborn service that provides for the care and management of maternal conditions consistent with ACOG guidelines, including pregnancies at all gestational ages and meets the requirements in 130.650.** **Maternal-Fetal Medicine Specialist shall mean an obstetrician/gynecologist who is licensed by the Massachusetts Board of Registration in Medicine and certified or an active candidate for certification in the subspecialty of maternal-fetal medicine by the American Board of Obstetrics and Gynecology.** Maternal-Newborn Service shall mean that part of the hospital in which care is routinely delivered to mothers and newborns.	The proposed change defines certain Level II services (Level II B services) that will provide enhanced services, including the capabilities to care for neonates of lower gestational age than those neonates cared for in Level II A services. The term ‘Perinatal Center’ is eliminated and replaced by ‘Level III Maternal and Newborn Service’. The proposed revision establishes the requirement that a neonatal intensive care unit be located in a hospital that also provides and meets the requirements of a level III maternal service.

CURRENT REGULATION	PROPOSED CHANGES	RATIONALE FOR CHANGE
	Neonatal Fellow shall mean a physician licensed by the Massachusetts Board of Registration in Medicine who is completing a fellowship in neonatology. Neonatal Intensive Care Unit shall mean a unit located either in a hospital with a Level III maternal and newborn service or a freestanding pediatric hospital with neonatalogy specialty services that provides a comprehensive range of specialty and subspecialty services to severely ill infants. **Neonatal Nurse Practitioner shall mean an individual authorized by the Massachusetts Board of Registration in Nursing under MGL c. 112, 80B and authorized to practice as a nurse practitioner pursuant to 244 CMR 4.00 et seq. who holds certification as a neonatal nurse practitioner from a nationally recognized accrediting body acceptable by the Board.** **Neonatologist shall mean a pediatrician licensed by the Massachusetts Board of Registration in Medicine who is either certified or an active candidate for certification in neonatology by the American Board of Pediatrics** **Obstetrician shall mean a physician licensed by the Massachusetts Board of Registration in Medicine and certified or an active candidate for certification by the American Board of Obstetrics and Gynecology.** **Pediatrician shall mean a physician licensed by the Massachusetts Board of Registration in Medicine who is either certified or an active candidate for certification in neonatology by the American Board of Pediatrics.** Postpartum Unit shall mean that part of a maternal-newborn service that is used exclusively for postpartum care. **Postpartum beds include beds located in labor-delivery-recovery–postpartum rooms.** Recovery Area shall mean a specifically designated area within the labor-delivery suite used to care for patients recovering immediately after delivery.	To better ensure quality of maternal care, the proposed revision establishes the requirement that a neonatal intensive care unit be located in a hospital that also has the capabilities to care for high risk mothers. Additional language added for clarity.

CURRENT REGULATION	PROPOSED CHANGES	RATIONALE FOR CHANGE
	Recovery Infant shall mean an infant who required ~~a more~~ acute **care services** ~~level facility~~ for diagnosis and treatment, whose acute phase of illness has passed, and who now needs limited therapeutic intervention prior to discharge Retrotransferred Infant shall mean an infant who required transfer to a more acute level facility for diagnosis or treatment not available in the birth hospital, who no longer requires these services, and is transferred back to the birth hospital or to another hospital with the level of service meeting his/her needs. Risk assessment of the infant shall mean the process of ~~**medically**~~ evaluating the newborn to determine whether he/she has special risks or combination of risks for adjustment to extrauterine life, health or survival in order to determine the need for specialized services and which includes a review of social, economic, genetic, and medical history findings prior to delivery or within the newborn period Risk assessment of the maternal patient shall mean the process of medically evaluating the mother to determine whether she has special risks or combination of risks to her own health and well-being or to that of the fetus in order to determine the need for specialized services and which includes a review of social, economic, genetic and/or medical conditions during the antepartal, intrapartal and/or postpartal periods Special Care Nursery shall mean a nursery that is specially equipped and staffed to offer a variety of specialized services to moderately ill infants who do not require intensive care. Stable-growing Infant shall mean the medically stable infant with a low birth weight who requires only a weight increase to be ready for discharge. Transfer Infant shall mean any infant who is transferred from the birth hospital because he/she requires ~~the~~ **acute services for** diagnos~~tic~~**is** ~~-~~and treatment **not available at the birth hospital**. ~~capabilities of a more acute~~	

CURRENT REGULATION	PROPOSED CHANGES	RATIONALE FOR CHANGE
	~~level facility~~ **Well Newborn Nursery shall mean a room housing newborns who do not need continuing care, special care or intensive care newborn services.**	
Designated Service levels shall mean the following levels of care based on services provided by the hospital. The designated level of care for each maternal-newborn service shall be approved by the Department of Public Health.	~~Designated Service levels shall mean the following levels of care based on services provided by the hospital. The designated level of care for each maternal-newborn service shall be approved by the Department of Public Health.~~	Definition eliminated here and relocated
(1) (a) Level I - Community-Based Maternal-Newborn Service shall mean a service that	~~(1) (a) Level I - Community-Based Maternal-Newborn Service~~ **~~includes Level I A and Level I B services. A Level I A service~~** ~~shall mean a service that~~	Definition eliminated here and relocated
provides care to routine maternal patients as well as those with actual or potential problems, the management of which are medically assessed as being within the capabilities of the Level I facility. A Level I service cares for infants born at that hospital who do not need the specialized services of a Level II or III service as defined in 105 CMR 130.601(A) and for retrotransferred stable - growing or recovery infants.	~~provides care to routine maternal patients as well as those with actual or potential problems, the management of which are medically assessed as being within the capabilities of the Level I facility. A Level I service cares for infants born at that hospital who do not need the specialized services of a Level II or III service as defined in 105 CMR 130.601(A) and for retrotransferred stable - growing or recovery infants.~~	Definition eliminated here and relocated
(b) Level IB - Community-Based Maternal-Newborn Service shall mean a Level I maternal service with a continuing care nursery. A service shall be eligible for designation as a Level IB service if one of the following conditions is met:	~~(b) Level IB - Community-Based Maternal-Newborn Service shall mean a Level I maternal service with a continuing care nursery. A service shall be eligible for designation as a Level IB service if one of the following conditions is~~ met:	Definition eliminated here and relocated Volume requirement for Level IB is eliminated. By eliminating the volume standard, all community hospitals committed to providing enhanced services and meeting the quality of care standards for a Level IB service have the opportunity to offer such care to its community.
(i) the service has a minimum of 1200 births per year in any one of the past three years;	~~(i) the service has a minimum of 1200 births per year in any one of the past three years;~~	
(ii) the service has satisfactorily demonstrated to the Department that a minimum volume of 1200 births per year will be reached in the next three years; or	~~(ii) the service has satisfactorily demonstrated to the Department that a minimum volume of 1200 births per year will be reached in the next three years; or~~	
(iii) the service has satisfactorily demonstrated to the Department that the hospital's role in assuring access to maternal and newborn care warrants such designation.	~~(iii) the service has satisfactorily demonstrated to the Department that the hospital's role in assuring access to maternal and newborn care warrants such designation.~~	
Continuing Care Nursery shall mean a nursery that is specially equipped and staffed to offer a variety of specialized services as specified in 105 CMR 130.630(E) to mild or moderately ill infants born at the level IB hospital or to retrotransferred stable - growing or recovery infants who do not require intensive or special care. All infants requiring mechanical ventilation shall be	~~Continuing Care Nursery shall mean a nursery that is specially equipped and staffed to offer a variety of specialized services as specified in 105 CMR 130.630(E) to mild or moderately ill infants born at the level IB hospital or to retrotransferred stable - growing or recovery infants who do not require~~	Definition relocated

CURRENT REGULATION	PROPOSED CHANGES	RATIONALE FOR CHANGE
transferred to a Level III service.	~~intensive or special care. All infants requiring mechanical ventilation shall be transferred to a Level III service.~~	
(2) Level II - Community-Based Maternal-Newborn Service with a Special Care Nursery shall mean a service that provides care for routine maternal and newborn patients, as well as for the majority of patients with potential and actual problems. A level II unit provides service both to infants born at the Level II hospital and to mothers and infants transferred in from Level I and Level IB services. A service shall be eligible for designation as a Level II service with a special care nursery if one of the following conditions is met:	~~(2) Level II - Community-Based Maternal-Newborn Service with a Special Care Nursery shall mean a service that provides care for routine maternal and newborn patients, as well as for the majority of patients with potential and actual problems. A level II unit provides service both to infants born at the Level II hospital and to mothers and infants transferred in from Level I and Level IB services.~~	Definition eliminated here and relocated
(a) the service has a minimum of 1500 births per year in any one of the past three years;	~~(a) the service has a minimum of 1,500 births per year in any one of the past three years~~	Volume element of definition eliminated here and relocated
(b) the service has satisfactorily demonstrated to the Department that a minimum volume of 1500 births per year will be reached in the next three years; or	~~(b) the service has satisfactorily demonstrated to the Department that a minimum volume of 1500 births per year will be reached in the next three years; or~~	
(c) the service has satisfactorily demonstrated to the Department that the hospital's role in assuring access to maternal and newborn care warrants such designation.	~~(c) the service has satisfactorily demonstrated to the Department that the hospital's role in assuring access to maternal and newborn care warrants such designation.~~	
Special Care Nursery shall mean a nursery that is specially equipped and staffed to offer a variety of specialized services to moderately ill infants who do not require intensive care. All infants requiring mechanical ventilation shall be transferred to a Level III service.	~~Special Care Nursery shall mean a nursery that is specially equipped and staffed to offer a variety of specialized services to moderately ill infants who do not require intensive care. All infants requiring mechanical ventilation shall be transferred to a Level III service.~~	Definition eliminated here and relocated
(3) Level III - Perinatal Center and/or Neonatal Intensive Care Unit	(3) ~~Level III - Perinatal Center and/or Neonatal Intensive Care Unit~~	Definition eliminated here and relocated
(a) Perinatal Center shall mean a hospital service that provides care and services to mothers and newborns of all risk assessment levels, including those with unusual/severe complications or anomalies. The Perinatal Center shall offer a comprehensive range of specialty and subspecialty services to maternal and newborn patients from the center or referred from Level I-II services. The Perinatal Center shall be located in a hospital which has capabilities to manage the maternal patient requiring intensive care. The Perinatal Center shall maintain a Neonatal Intensive Care Unit.	~~(a) Perinatal Center shall mean a hospital service that provides care and services to mothers and newborns of all risk assessment levels, including those with unusual/severe complications or anomalies. The Perinatal Center shall offer a comprehensive range of specialty and subspecialty services to maternal and newborn patients from the center or referred from Level I-II services. The Perinatal Center shall be located in a hospital which has capabilities to manage the maternal patient requiring intensive care. The Perinatal Center shall maintain a Neonatal Intensive Care Unit~~	Definition eliminated here and relocated.

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(b) Neonatal Intensive Care Unit shall mean a unit that provides a comprehensive range of specialty and subspecialty services to severely ill infants. The Neonatal Intensive Care Unit shall be located within either a Perinatal Center or a facility with a Level III pediatric service.	~~(b) Neonatal Intensive Care Unit shall mean a unit that provides a comprehensive range of specialty and subspecialty services to severely ill infants. The Neonatal Intensive Care Unit shall be located within either a Perinatal Center or a facility with a Level III pediatric service.~~	Definition eliminated here and relocated
The Level III Perinatal Center and/or Neonatal Intensive Care Unit shall assume responsibilities for consultation, transport and professional educational offerings to the Level I and II services with which it has collaboration agreements.	~~The Level III Perinatal Center and/or Neonatal Intensive Care Unit shall assume responsibilities for consultation, transport and professional educational offerings to the Level I and II services with which it has collaboration agreements.~~	Requirement amended and relocated to other section
Family-centered Care shall mean a method of providing services which fosters the establishment and maintenance of parent-newborn-family relationships. The family may consist of the father, mother and child and/or include other identified support persons (biologically or nonbiologically related) for the mother and infant.	~~Family-centered Care shall mean a method of providing services which fosters the establishment and maintenance of parent-newborn-family relationships. The family may consist of the father, mother and child and/or include other identified support persons (biologically or nonbiologically related) for the mother and infant.~~	Definition eliminated here and relocated
Maternal-Newborn Service shall mean that part of the hospital in which care is routinely delivered to mothers and newborns.	~~Maternal-Newborn Service shall mean that part of the hospital in which care is routinely delivered to mothers and newborns~~	Definition eliminated here and relocated
Risk Assessment.		
(1) Risk assessment of the infant shall mean the process of medically evaluating the newborn to determine whether he/she has special risks or combination of risks for adjustment to extrauterine life, health or survival in order to determine the need for specialized services and which includes a review of social, economic, genetic, and medical history findings prior to delivery or within the newborn period.	(1) ~~Risk assessment of the infant shall mean the process of medically evaluating the newborn to determine whether he/she has special risks or combination of risks for adjustment to extrauterine life, health or survival in order to determine the need for specialized services and which includes a review of social, economic, genetic, and medical history findings prior to delivery or within the newborn period.~~	Definition eliminated here and relocated
(2) Risk assessment of the maternal patient shall mean the process of medically evaluating the mother to determine whether she has special risks or combination of risks to her own health and well-being or to that of the fetus in order to determine the need for specialized services and which includes a review of social, economic, genetic and/or medical conditions during the antepartal, intrapartal and/or postpartal periods.	~~(2) Risk assessment of the maternal patient shall mean the process of medically evaluating the mother to determine whether she has special risks or combination of risks to her own health and well-being or to that of the fetus in order to determine the need for specialized services and which includes a review of social, economic, genetic and/or medical conditions during the antepartal, intrapartal and/or postpartal periods.~~	Definition eliminated here and relocated
Types of Patients	~~Types of Patients~~	
(1) Gynecology Patient shall mean any woman with or suspected of having a health problem	~~(1) Gynecology Patient shall mean any woman with or suspected of having~~	Definition eliminated here and relocated

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related to her reproductive organs.	~~a health problem related to her reproductive organs~~	
(2) Recovery Infant shall mean an infant who required a more acute level facility for diagnosis and treatment, whose acute phase of illness has passed, and who now needs limited therapeutic intervention prior to discharge.	(2) ~~Recovery Infant shall mean an infant who required a more acute level facility for diagnosis and treatment, whose acute phase of illness has passed, and who now needs limited therapeutic intervention prior to discharge~~.	Definition eliminated here and relocated
(3) Retrotransferred Infant shall mean an infant who required transfer to a more acute level facility for diagnosis or treatment not available in the birth hospital, who no longer requires these services, and is transferred back to the birth hospital or to another hospital with the level of service meeting his/her needs.	~~(3) Retrotransferred Infant shall mean an infant who required transfer to a more acute level facility for diagnosis or treatment not available in the birth hospital, who no longer requires these services, and is transferred back to the birth hospital or to another hospital with the level of service meeting his/her needs.~~	Definition eliminated here and relocated
(4) Stable-growing Infant shall mean the medically stable infant with a low birthweight who requires only a weight increase to be ready for discharge.	~~(4) Stable-growing Infant shall mean the medically stable infant with a low birth weight who requires only a weight increase to be ready for discharge.~~	Definition eliminated here and relocated
(5) Transfer Infant shall mean any infant who is transferred from the birth hospital because he/she requires the diagnostic and treatment capabilities of a more acute level facility.	~~(5) Transfer Infant shall mean any infant who is transferred from the birth hospital because he/she requires the diagnostic and treatment capabilities of a more acute level facility.~~	Definition eliminated here and relocated
Types of Patient Care Rooms.	~~Types of Patient Care Rooms.~~	
(1) Birthing Room shall mean a room designed to provide family-centered care in a "homelike" environment for low-risk mothers throughout the labor, delivery and immediate recovery periods. Local and pudendal anesthesia only shall be administered in a birthing room.	(1~~) Birthing Room shall mean a room designed to provide family-centered care in a "homelike" environment for low-risk mothers throughout the labor, delivery and immediate recovery periods. Local and pudendal anesthesia only shall be administered in a birthing room~~.	Definition eliminated here and relocated
(2) Delivery/Cesarean Birth Room shall mean a room staffed and equipped to handle low-risk to high-risk deliveries, including cesarean births, and have capabilities of administering all forms of anesthesia, including inhalation agents.	~~(2) Delivery/Cesarean Birth Room shall mean a room staffed and equipped to handle low-risk to high-risk deliveries, including cesarean births, and have capabilities of administering all forms of anesthesia, including inhalation agents.~~	Definition eliminated here and relocated
(3) Labor Room shall mean an area in which the mother experiences the first stage of labor.	~~(3) Labor Room shall mean an area in which the mother experiences the first stage of labor.~~	Definition eliminated here and relocated
(4) Labor-Delivery Suite shall mean that part of a maternal and newborn service used to care for patients during labor, delivery and recovery. It shall include physically contiguous labor room(s), delivery/cesarean birth room(s) and ancillary facilities.	~~(4) Labor-Delivery Suite shall mean that part of a maternal and newborn service used to care for patients during labor, delivery and recovery. It shall include physically contiguous labor room(s), delivery/cesarean birth room(s) and ancillary facilities.~~	Definition eliminated here and relocated
(5) Labor-Delivery-Recovery Room shall mean a room designed, staffed and equipped to care for mothers, newborns and their families throughout the labor, delivery and recovery periods. Anesthesia use shall be limited to the local and regional modes.	~~(5) Labor-Delivery-Recovery Room shall mean a room designed, staffed and equipped to care for mothers, newborns and their families throughout the labor, delivery and recovery periods. Anesthesia use shall be limited to the local and regional modes.~~	Definition eliminated here and relocated
(6) Labor-Delivery-Recovery-Postpartum Room (Single-Room Maternity Care) shall mean a	~~(6) Labor-Delivery-Recovery-Postpartum Room (Single-Room Maternity~~	Definition eliminated here and relocated

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room designed, staffed and equipped to care for mothers, newborns and their families throughout the labor, delivery, recovery and postpartum periods. Anesthesia use shall be limited to the local and regional modes.	~~Care) shall mean a room designed, staffed and equipped to care for mothers, newborns and their families throughout the labor, delivery, recovery and postpartum periods. Anesthesia use shall be limited to the local and regional modes.~~	
(7) Postpartum Unit shall mean that part of a maternal-newborn service, which is used, exclusively for postpartum care.	~~(7) Postpartum Unit shall mean that part of a maternal-newborn service which is used exclusively for postpartum care.~~	Definition eliminated here and relocated
(8) Recovery Area shall mean a specifically designated area within the labor-delivery suite used to care for patients recovering immediately after delivery.	~~(8) Recovery Area shall mean a specifically designated area within the labor-delivery suite used to care for patients recovering immediately after delivery.~~	Definition eliminated here and relocated
130.605: Department Designation of Level of Maternal/Newborn Care in a Hospital		
(A) The Department shall designate the level of maternal-newborn care of each hospital subject to Department licensure which provides maternal and/or newborn services as defined in 105 CMR 130.026.		
(B) As directed by the Department, each hospital with maternal and/or newborn services shall file an application with the Department as to the level of maternal and/or newborn services for which the hospital requests designation.	(B) As directed by the Department, each hospital with maternal and/or newborn services shall file an application with the Department ~~as to~~ **identifying** the level of maternal and/or newborn services for which the hospital requests designation.	Minor language change
(C) The Department shall base such designation upon documentation submitted by each hospital of the nature of its maternal and/or newborn services and/or on-site evaluations by Department staff to determine compliance with the requirements of that level. The designation process is not intended to supercede the Department's authority to determine what constitutes a major service or a substantial change in service for determination of need purposes.	(C) The Department shall base such designation upon documentation submitted by each hospital of the nature ~~of~~ **regarding** its maternal and/or newborn services and/or on-site evaluations by Department staff to determine compliance with the requirements of that level. The designation process is not intended to **supersede** the Department's authority to determine what constitutes a major service or a substantial change in service for determination of need purposes.	Minor language change
(D) After the initial designation, the hospital shall re-apply for designation of its maternal and/or newborn services each time that it applies for renewal of its hospital license.	(D) After the initial designation, the hospital shall re-apply for designation of its maternal and newborn services **or a freestanding pediatric hospital with neonatology subspecialty** each time that it applies for renewal of its hospital license.	Language change for consistency
130.610: Establishment of Perinatal Advisory Committee	130.610: Establishment of **the Statewide** Perinatal Advisory Committee	

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The Department shall establish a Perinatal Advisory Committee to advise the Department on issues related to 105 CMR 130.615 through 130.628 (Maternal and Newborn Services). This Committee's membership shall be multidisciplinary. It shall include but not necessarily be limited to one or more members of the following groups: physicians, nurses, hospital administrators, and consumers. It shall be representative of the various parts of the state and all levels of perinatal care.	The Department shall establish a **state** Perinatal Advisory Committee to advise the Department on issues related to 105 CMR 130.615 through 130.628 (Maternal and Newborn Services). This Committee's membership shall be multidisciplinary. It shall include but not necessarily be limited to one or more members of the following groups: physicians, nurses, including nurse practitioners and nurse midwives, hospital administrators, and consumers. It shall be representative of the various parts of the state and all levels of perinatal care. **The Committee may develop operating procedures agreed upon by the Department that includes the opportunity for the regular rotation of committee members.**	The proposed additional language is intended to allow the Perinatal Advisory Committee and the Department the opportunity to establish operating procedures.
130 615: Patient/Family Services		
(A) The mother and infant shall receive care in the facility providing the level of service required for their unique medical needs.		
(B) Each hospital with a maternal-newborn service shall provide prenatal, postnatal and family-planning services either directly or through referral to an outside agency, including the following:		
(1) Preparation for the birthing experience for the mother, her family and/or significant other(s).		

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(2) Organized family-education program with associated written health instructional materials including, but not limited to: (a) Normal maternal care such as nutrition, rest and other basic needs. (b) Normal newborn care. (c) Abnormal symptoms in mother and/or infant for which the family should seek medical attention. (d) Anticipatory guidance regarding psychosocial family readjustment issues. (e) Family planning.	(2) Organized family-education program with associated written **and/or multimedia** health instructional materials including, but not limited to: (a) Normal maternal care such as nutrition, rest and other basic needs. (b) **Signs and symptoms of pre-term labor by 20 weeks, if applicable**. (c) Normal newborn **care and well child** care, **including recommended immunization and developmental assessment schedules and infant safety, including shaken baby syndrome.** (d) **Newborn screening information and materials provided at the time of admission prior to screening.** (e) Abnormal symptoms in mother and/or infant for which the family should seek medical attention, **including infant jaundice.** (f) Anticipatory guidance **and available resources for peripartum mental health issues and** ~~regarding psychosocial~~ family ~~re~~adjustment issues. (g) Family planning. (h) Dangers of second-hand smoke	Addition recognizes availability of more varied types of educational methods. Additions intended to highlight key categories of education elements.
(3) Breast-feeding instruction and support during hospitalization and provision of information on resources to assist the mother after discharge.	(3) ~~Breast-feeding~~ **Infant feeding** instruction and support during hospitalization and provision of information on resources to assist the mother **and family** after discharge, **including, for breast feeding mothers, community-based lactation consultant resources and availability of breast pumps.**	Revised language to the broader term 'Infant feeding' extends the requirements to include all types of feeding. Addition of more detailed standard enhances the quality of lactation care and services.
(4) Health education materials and activities shall be available in the languages of any non-English speaking group which comprises at least 10% of the population served by the maternal-newborn service.	(4) Health education materials and activities shall be available in the ~~languages of any non-English speaking group which comprises at least 10%~~ **major languages identified through the acute hospital's language needs assessment required under 105CMR 130.1103 (A) and literacy levels** of the population served by the maternal-newborn service.	Language requirement updated to meet related regulations. Also consideration of literacy levels will improve the outcome of patient education.
(D) Visitation policies for all service levels shall be designed to promote parent-infant contact and maintenance of the family unit, while providing privacy. These written policies shall be made available to families.	(D) Visitation policies for all service levels shall be designed to promote parent-infant contact and maintenance of the family unit, while providing **safety and** privacy. These written policies shall be made available to families.	Consideration of safety in visitation policies is intended to better protect mothers and infants.
(1) Hospitals shall provide educational information to all visitors indicating that the following	(1) Hospitals shall provide educational information to all visitors indicating	Language broadened to include consideration of

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should not visit: those who have been exposed to or have manifestation of communicable diseases for which the newborn is at particular risk, *e.g*., impetigo, varicella, tuberculosis, as well as vaccine-preventable diseases, particularly measles, mumps, rubella, pertussis and influenza.	that the following **persons** should not visit: those who have been exposed to or have manifestation of communicable diseases for which the newborn is at particular risk, *e.g*., impetigo, ~~**varicella**~~ , **active** tuberculosis**, acute respiratory disease**, as well as vaccine-preventable diseases, particularly measles, mumps, rubella, pertussis, **varicella** and influenza.	other respiratory diseases.
(2) The service shall have a policy to encourage and support the involvement of the father, and/or significant other(s) as designated by the mother, and permits contact with the mother and infant on a 24 hours a day basis throughout hospitalization.	~~(2) The service shall have a policy to encourage and support the involvement of the father, and/or significant other(s) as designated by the mother, and permits contact with the mother and infant on a 24 hours a day basis throughout hospitalization.~~	Eliminated here because the intent of this regulation is included in other section throughout the regulations.
(3) Siblings shall be permitted to visit the mother and newborn on a daily basis in accordance with written hospital visitation policy.		
(4) Policies for other visitors shall be formulated primarily for the support and comfort of mothers and infants.		
(5) The hospital shall have a policy for protecting pregnant women, mothers and infants from the effects of passive smoking.	~~(5) The hospital shall have a policy for protecting pregnant women, mothers and infants from the effects of passive smoking.~~	No longer necessary since all hospitals in Massachusetts are smoke-free.
	(5) The hospital shall have a policy to address the safety and security of mothers and infants.	Requirement for the hospital to develop such a policy was added to highlight the consideration of safety and security as an important component of quality care.
(E) Policies shall be established to ensure, that the staff provide ongoing information to families about the condition and progress of mother and/or infant. The policies shall also include a process to assist families in obtaining ongoing information about the condition of the infant who has been transferred to another level of care. Translation capabilities shall be available for any non-English group which comprises at least 10% of the population served by the maternal/newborn services. Services using nurse practitioners or pediatric residents shall inform families of the role and scope of clinical responsibilities of these health care providers.	(E) Policies shall be established to ensure, that the staff provide ongoing information to families about the condition and progress of mother and/or infant. The policies shall also include a process to assist families in obtaining ongoing information about the condition of the infant who has been transferred to another level of care. ~~Translation capabilities shall be available for any non-English group which comprises at least 10% of the population served by the maternal/newborn services~~. **For the limited English proficient population, the hospital shall ensure timely interpreter services are available.** Services using nurse practitioners or pediatric residents shall inform families of the role and scope of clinical responsibilities of these health care providers.	Language revised for clarity and updated.
(F) Nutritional consultation, including access to bicultural and bilingual personnel, shall be available for mothers and infants.	(F) **Culturally and linguistically appropriate n**utritional consultation, ~~including access to bicultural and bilingual personnel,~~ shall be available for mothers and infants.	Language updated for clarity
(F) Social work services, including access to bicultural and bilingual personnel, shall be available	(G) **Culturally and linguistically appropriate** social work services,	Language updated for clarity

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for mothers and infants..	~~including access to bicultural and bilingual personnel,~~ shall be available for mothers and infants.	
(H) Each maternal-newborn service shall have written protocols for the hospital management and support of patients from identified groups in the population served by the facility, who have special needs, e.g., adolescents, and mothers with known cognitive impairments, psychiatric or substance abuse problems.	(H) Each maternal-newborn service shall have written protocols for the hospital management, ~~and~~ support, **and discharge planning** of patients from identified groups in the population served by the facility, who have special needs, e.g., adolescents, mothers with known **physical or** cognitive impairments, substance abuse, psychiatric **diagnoses or psychosocial concerns.**	Language revised for clarity.
(I) Each service shall have written protocols for addressing the parenting needs of specific groups in the population served, such as adolescents, and mothers with known cognitive impairments, psychiatric or substance abuse problems.	~~(I) Each service shall have written protocols for addressing the parenting needs of specific groups in the population served, such as adolescents,~~ **~~incarcerated or homeless mothers~~** ~~and mothers with known cognitive impairments, psychiatric~~ **~~diagnosis or physical~~** ~~or substance abuse problems.~~	The requirement is eliminated here and combined with (H) above.
(J) Each service shall have a written policy that provides for discharge planning and referrals to community agencies.	(J) Each service shall have a written policy that provides for discharge planning and referrals to community agencies **and healthcare providers, including lactation consultants as needed.**	The addition of healthcare providers broadens the requirement to better ensure the quality of the discharge plan.
(K) Mothers of babies with special health needs shall receive information about appropriate resources such as early intervention, self-help groups, and other community contacts as soon as possible after delivery.		
(L) Each service shall provide support and referral for the family experiencing perinatal grief because of the death of a neonate. All families shall be given the opportunity to see, hold and participate in the care of their infant during and after the dying process.		
	(M) The maternal and newborn service shall provide information about the Women, Infants and Children (WIC) program's benefits and services to all mothers. As appropriate, staff shall refer mothers to the WIC program closest to their residence.	The addition of this requirement will better ensure eligible mothers receive benefits and services available through the WIC program.
130.616: Administration and Staffing		
(A) Perinatal Committee.	(A) Perinatal Committee.	

CURRENT REGULATION	PROPOSED CHANGES	RATIONALE FOR CHANGE
(1) Each maternal-newborn service shall establish a multidisciplinary perinatal committee or its equivalent responsible for developing a coordinated approach to maternal-newborn care including but not limited to the following: (a) Long-range program planning. (b) Establishing, approving and planning the implementation of policies and procedures. © Reviewing and evaluating maternal and newborn care delivered by the service, including appropriateness of multidisciplinary staffing patterns to ensure safe patient care. (d) Providing a mechanism to encourage and obtain community input on the service. (2) The committee shall meet at least quarterly and include physician and nurse leaders from both the maternal and newborn services and representatives from other services as appropriate.	(1) Each maternal-newborn service shall establish a multidisciplinary perinatal committee or its equivalent responsible for developing a coordinated approach to maternal-newborn care including but not limited to the following: (a) **Developing a statement of philosophy and objectives of family-centered care.** (b) Long-range program planning. (c) Establishing, approving**, reviewing** and planning the implementation of policies and procedures. (d) Reviewing and evaluating **process and outcome of** maternal and newborn care delivered by the service, including appropriateness of multidisciplinary staffing patterns to ensure safe patient care. (e) **Reviewing service data and statistics** **(f)** Providing a mechanism to encourage and obtain community input on the service. **(g) Participating in the evaluation of staff education needs** (2) The committee shall meet at least quarterly and include physician and nurse leaders from both the maternal and newborn services and representatives from other services as appropriate.	Additions intended to clarify and strengthen the functions of the committee, in particular to support family-centered care, outcome evaluation and education.
(B) Written Collaboration Agreements.	(B) Written Collaboration **andTransfer** Agreements.	This section re-titled to more accurately reflect the patient transfer aspects of care included in the section.

CURRENT REGULATION	PROPOSED CHANGES	RATIONALE FOR CHANGE
(1) Each hospital with a maternal-newborn service which is not designated as a perinatal center shall develop a written collaboration agreement with one or more designated perinatal center(s), including provisions for consultation, guidelines for maternal and newborn transfer, ongoing patient-centered communications, and provision for professional educational offerings (by the perinatal center). In its collaboration agreement with a level III service, a hospital that is designated by the Department as a level II maternal and newborn service and that retains neonatal nurse practitioners to provide on-site delivery room and special care nursery coverage shall include provisions for administrative and clinical collaboration specific to the neonatal nurse practitioners. At a minimum specific provisions shall include the planned schedule of rotation of the neonatal nurse practitioner to the level III service and the mechanism for the periodic evaluation of the neonatal nurse practitioner's performance as required under 105 CMR 130.640(B)(3)(b)(iii). (2) Collaboration agreements shall include provisions for a joint program of quality assurance monitoring with a focus on outcomes. (3) Guidelines for maternal and newborn transfer shall reflect recommendations from the quality assurance activities. (4) Maternal-newborn centers located close to a perinatal center in another state may develop an agreement with that center, provided the center meets the applicable regulations for that state. (5) Copies of written collaboration agreements shall be submitted to the Department upon request.	(1) Each hospital with a maternal-newborn service which is not designated as a ~~perinatal center~~ **Level III service** shall develop a written collaboration/**transfer** agreement with **at least** one **primary** ~~or more designated perinatal center(s)~~ **Level III maternal and newborn service. The agreement shall** includ~~inge~~ provisions for consultation; guidelines for maternal and newborn transfer**, including provision of relevant medical information** and ongoing patient-centered communications **before, during and after transport;** and provision for professional educational offerings ~~(by the perinatal center~~). (2) In its collaboration**/transfer** agreement with a level III service, a hospital that is designated by the Department as a level II maternal and newborn service and that retains neonatal nurse practitioners to provide on-site delivery room and special care nursery coverage shall include provisions for administrative and clinical collaboration specific to the neonatal nurse practitioners. At a minimum specific provisions shall include the planned schedule of rotation of the neonatal nurse practitioner to the level III service and the mechanism for the periodic evaluation of the neonatal nurse practitioner's performance as required under 105 CMR 130.640(B)(3)(b)(iii). (3) Collaboration**/transfer agreements between hospitals that regularly transfer patients** shall include provisions for ~~a joint program of quality assurance~~ monitoring **the quality of care provided to transfers** with a focus on outcomes. (4) Guidelines for maternal and newborn transfer shall reflect recommendations from the quality assurance activities. **The guidelines shall address the following: initiation of transfer; acceptance of transfer; delineation of responsibilities of referring hospital, transport team and receiving hospital; patient consent; transfer procedures and retro-transfer policy and procedures.** (5) **The Level III hospital receiving a request for a transfer shall make every effort to accept all medically appropriate obstetrical and neonatal patients for which they have the resources to provide the appropriate level of care. If no bed is available, upon the request of the referring hospital, the Level III hospital shall offer assistance and advice on possible alternative Level III hospitals for transfer**	Section strengthened to include more specific requirements and safeguards (transfer of information and communication; written guidelines) for patients transferred from one hospital to another.

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	(6) **Level III hospitals receiving transfers shall make every effort to return maternal and neonatal patients to the transferring hospital when it is clinically appropriate to do so. The hospitals shall inform the patient and/or patient's family that the patient may be transferred back when such a retro-transfer is medically appropriate.** (7) Maternal-newborn centers located close to a ~~perinatal center~~ **level III service** in another state may develop an agreement with that center, provided the center meets the applicable regulations for that state. (8) Copies of **up-to-date** written collaboration**/transfer** agreements shall be submitted to the Department upon request.	In support of family centered care, the section adds a requirement that supports the return of patients to their community hospital when it is medically safe to do so.
(c) Administrative Policies. Each maternal-newborn service shall develop and implement written administrative policies which include provisions for the following:		
(1) Staff privileges granted to each physician, nurse midwife and each nurse practicing in an advanced practice role shall specify those areas in which his/her practice is limited and/or requires consultation before therapeutic intervention.		
(2) Documentation of informed consent for both maternal and newborn care.		
(3) On-site presence, on a 24 hours a day basis, of at least one professional staff member with documented skills in neonatal resuscitation.	(3) On-site availability, on a 24 hours a day basis, of at least one professional staff member ~~with documented skills in neonatal resuscitation~~ **who is certified in neonatal resuscitation by a recognized program, such as the American Academy of Pediatrics' Neonatal Resuscitation Program (NRP)**	The language is updated to recognize the most current national neonatal resuscitation skills training program.
(4) Management of high-risk mothers and newborns including identification of high risk patients and consultation with appropriate specialists for the purpose of determining treatment and/or the need to transfer to the facility offering the level of care required by the patient. Such policies shall include use of appropriate alternative facilities, if beds in the usual affiliated transfer institution are not available.	(4) Management of high-risk mothers and newborns including identification of high-risk patients and consultation with appropriate specialists for the purpose of determining treatment and/or the need to transfer to the **hospital's specialized medical, surgical or critical care services or to another** facility offering the level of care required by the patient. Such policies shall include use of appropriate alternative facilities, if beds in the usual affiliated transfer institution are not available.	The additional language recognizes that hospitals need to develop policies covering circumstances when patients on the maternal and newborn service may need consultation with or transfer to another service within the same hospital.
(5) Placement of prenatal patients (hospitalized for pregnancy-related conditions) on the maternal-newborn service.	(5) Placement **and care** of **a)** prenatal patients (hospitalized for pregnancy-related conditions) on the maternal-newborn service **and b) prenatal patients hospitalized for medical/surgical conditions that are not pregnancy-related.**	The additional language recognizes that hospitals need to develop policies covering circumstances when prenatal patients are admitted to the hospital for medical or surgical conditions that are not pregnancy-related.
(6) Admission of the previously-discharged (to home), or retrotransferred recovery		

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stable-growing infant under the following circumstances:		
(a) The infant previously discharged to home may be readmitted to the newborn nursery provided that the infant is within two weeks of discharge from that nursery, has a noninfectious condition and is approved for readmission by the medical director of the newborn service and the maternal-newborn nursing administrator or their designee(s).		
(b) The retrotransferred recovery infant may be admitted to the newborn nursery upon written order of the attending physician and approval of the medical director of the newborn service and the maternal-newborn nursing administrator or their designee(s).		
(c) The newborn service may admit a retrotransferred recovery infant who was not born at that hospital, providing the hospital offers the level of service required by the infant and is geographically close to the parents.		
	d) The retrotransferred infant shall be managed with contact precautions (in accordance with the most recent version of the Centers for Disease Control and Prevention guidelines) until the infection or colonization with an antibiotic-resistant organism has been ruled out.	The language adds the updated infection control reference for infants returning to the birth hospital after care at a different hospital.
(7) Provision for a written discharge summary to another maternal-newborn service at the time of the patient's transfer or to the primary care provider at the time of the patient's discharge. The summary shall include diagnosis and treatment provided.		
(D) Patient Care Policies. Each maternal-newborn service shall develop and implement written patient care policies and procedures which shall include provisions for the following:	(D) Patient Care Policies. Each maternal-newborn service shall develop and implement written patient care policies and procedures, **supported by the evidence based resources,** which shall include provisions for the following:	The added language strengthens the requirement by recognizing the need to use evidenced-based resources to back up patient care policies.
(1) Use of medication and parenteral therapy during labor. Routine standing orders shall not be permitted.	**(1) Triage of patients presenting to the service to establish the diagnosis of labor, need for admission, transfer and/or other care management.** **(2) Policy addressing communication and decision making responsibilities with specified chain of command.** (3) Use of **analgesic** medication and parenteral therapy during labor. Routine standing orders shall not be permitted	Key policies effecting the quality of patient care added to this section on patient care policies.
(2) Use of electronic fetal monitoring with guidelines for interpretation.	(4) **Fetal assessment modalities including the** use of electronic fetal monitoring with guidelines for interpretation. (5) **Elective Cesarean birth** **(6) Criteria for induction and augmentation of labor** **(7) Initiation and management of epidural analgesia and regional anesthesia**	

CURRENT REGULATION	PROPOSED CHANGES	RATIONALE FOR CHANGE
(3) Nursing management of the following emergencies:	~~**(3)** Nursing management of the following emergencies:~~	
(a) Maternal/newborn cardiopulmonary distress and arrest. (b) Fetal distress. (c) Prolapsed umbilical cord. (d) Maternal/newborn metabolic crisis. (e) Maternal/newborn seizure. (f) Precipitous birth. (g) Psychological crisis. (h) Emergency cesarean birth. (i) Anesthesia and analgesia related emergencies. (j) Maternal hemorrhage and shock.	~~(a) Maternal/newborn cardiopulmonary distress and arrest.~~ ~~(b) Fetal distress.~~ ~~(c) Prolapsed umbilical cord.~~ ~~(d) Maternal/newborn metabolic crisis.~~ ~~(e) Maternal/newborn seizure.~~ ~~(f) Precipitous birth.~~ ~~(g) Psychological crisis.~~ ~~(h) Emergency cesarean birth.~~ ~~(i) Anesthesia and analgesia related emergencies.~~ ~~(j) Maternal hemorrhage and shock.~~	
(4) Criteria for when the presence of a pediatrician at the birth is required.	**(8)** Criteria for when the presence of ~~a pediatrician~~ **specialized personnel are** ~~at the birth is~~ required **at birth.**	The change to the term 'specialized personnel' is intended to be more inclusive to cover more than just a pediatrician but also neonatalogists, respiratory therapists, anesthesiologists etc.
(5) Care of the mother in the immediate postpartal period.	~~(5)~~ **(9)** Care of the mother in the immediate ~~postpartum~~ **post partum** period, **including immediate post-surgical recovery care.**	Language added to ensure inclusion of care of mothers undergoing surgical births.
(6) Immediate nursing assessment of the newborn by a registered nurse with specific criteria for notifying a pediatrician.	(**10**) Immediate nursing assessment of the newborn by a registered nurse with specific criteria for notifying a ~~pediatrician~~. **pediatric provider.**	Clarification
(7) Support of lactation initiation and maintenance for mothers who choose breastfeeding. Such policies shall provide for the following:	**(11)** Support of lactation initiation and maintenance for mothers who choose breastfeeding. Such policies shall provide for the following	Renumbered
(a) No standing orders for antilactation drugs.	(a) No standing orders for antilactation drugs.	
(b) Encouragement of breastfeeding as soon after birth as the baby is interested.	(b) **Unless medically contraindicated, e**ncouragement of breastfeeding as soon after birth as the baby is interested **and encouragement and assistance with milk expression, if mother and baby are separated.**	Language change to clarify and strengthen the requirement,
(c) Frequent nursing periods, based on the infant's needs.		
(d) Supplemental bottle feeding for medical reasons or on request of the mother only.		
(e) Sample formula and/or formula equipment distributed to breast-feeding mothers only when an individual physician order is written or on the request of the mother.	(e) **Use of commercial formula marketing materials, such as** sample formula ~~and/or~~, formula equipment shall not be permitted **for breast feeding mothers** except that **discharge gift bags from commercial formula companies may be** distributed to these mothers only when an individual physician order is written or on the request of the mother.	Language change to clarify and strengthen the requirement,
(8) Care of the newborn. Such policies shall provide for the following:	**(12)** Care of the newborn. Such policies shall provide for the following:	Renumbered
(a) Apgar scoring.		
(b) Thermoregulation.		

CURRENT REGULATION	PROPOSED CHANGES	RATIONALE FOR CHANGE
© Eye prophylaxis for ophthalmia neonatorum.		
(d) Collection of cord blood sample.		
(e) Vitamin K administration.		
(f) Infant identification via a duplicate method.	(f) ~~Infant identification via a duplicate method~~. **Infant security policies and procedures developed in conjunction with the hospital's security and pediatric department. At a minimum, the policy shall address: a process for identifying the newborn at the time of delivery; use of an acceptable identification system; procedure for re-banding an infant; identification of individuals who can remove a newborn from the nursery; visitation policies outlining who is allowed to visit and when; and a plan for educating parents regarding the security procedures.**	The requirement is expanded to recognize the enhanced need for hospitals to develop and implement comprehensive policies and procedures to better ensure infant safety and security.
(g) Promotion of parent-newborn contact.		
(h) Infant feeding (including flexible schedule per parent's request), output measurement and skin care.		
(i) Comfort measures and reduction of pain and trauma during invasive procedures.		
(j) Complete physical examination by a physician within 24 hours of birth or upon admission, including infants who are retrotransferred.		
(k) Stabilization and management of the infant requiring transfer including the opportunity for the family to see and touch the infant before transfer.		
(l) Hearing screening.	(l) Hearing screening. **(m) blood screening** **(n) Appropriate administration of hepatitis B vaccine and hepatitis B immune globulin to all infants according to the recommendation of the Centers for Disease Control Advisory Committee in Immunization Practices and the Massachusetts Immunization Program.**	Additions update and strengthen the requirement.
(9) Planning for discharge, including documentation of follow-up care arrangements for both mother and infant.	~~9)~~ **(13)** Planning for discharge, including documentation of follow-up care arrangements **and referral to appropriate community resources and providers** for both mother and infant.	Language change to clarify and strengthen the requirement
(10) Admission and/or treatment of patients who have delivered outside of the maternal-newborn service, including home births.	~~(10)~~ **(14)** Admission and/or treatment of patients who have delivered outside of the maternal-newborn service **or hospital**. ~~, including home births~~.	Phrase is not necessary since home births are considered out of hospital delivers.
(11) Use of the maternity service for gynecology patients. Gynecology patients shall not be routinely cared for on a maternity unit; however, in the event that they are placed on the unit, they shall be in rooms separate from maternity patients and the following shall be required:	~~(11)~~ **(15)** Use of the maternity service for gynecology patients. Gynecology patients shall not be routinely cared for on a maternity unit; however, in the event that they are placed on the unit, they shall be in rooms separate from maternity patients and the following shall be required:	Renumbered

CURRENT REGULATION	PROPOSED CHANGES	RATIONALE FOR CHANGE
(a) Provision for the availability of maternity beds to meet patient needs.		
(b) Admission guidelines with exclusionary criteria for patients:		
(i) requiring radioactive implants;		
(ii) exposed to or suffering from active communicable disease with airborne, contact or fecal-oral modes of transmission; or	~~(ii) exposed to or suffering from active communicable disease with airborne, contact or fecal-oral modes of transmission; or~~ **who have active infection or are colonized with a potentially virulent or drug-resistant organism that would put others at risk, for which appropriate and consistent use of recommended infection control practices cannot be assured; or**	Language change to clarify, strengthen the requirement and remain consistent with Centers for Disease Control recommendations.
(iii) requiring significant medical or surgical care in addition to gynecologic care;		
(iii) Visiting policies shall be consistent with those on the maternity service.	~~(iii)~~ **(iv)** Visiting policies shall be consistent with those on the maternity service.	
	(16) Protocols to assure that the care of obstetrical patients hospitalized for medical/surgical conditions is coordinated, including consultation with obstetrical services medical and nursing staff. **(17) Offering and administrating a dose of measles-mumps-rubella (MMR) vaccine to all mothers who are rubella antibody negative prior to discharge.**	Consistent with current standards of practice. Addition makes requirements consistent with Centers for Disease Control recommendations.
	(18) Policies for the safe and secure storage of formula and breast milk.	Addition added to recognize current standards
(E) Quality Assurance Program.	(E) Quality Assurance **and Education** Program.	
(1) Each maternal-newborn service shall have an ongoing documented quality assurance program including problem identification, action plans, evaluation and follow-up. A multi-disciplinary approach shall be required. (2) The quality assurance program shall include at least an annual review of transfer cases, management of cases, and educational programs and protocols among facilities which transport to one another pursuant to collaboration agreements. (3) Outcome statistics including neonatal and perinatal mortality, as well as appropriateness of neonatal and maternal transfers, shall be compiled in a standardized manner and reviewed periodically by the hospital perinatal committee. Neonatal and maternal deaths after transfer or discharge from the facility (within first 28 days of birth) shall be included in the statistics	(1) Each maternal-newborn service shall have an ongoing documented quality assurance program including problem identification, action plans, evaluation and follow-up. A multi-disciplinary approach shall be required. (2) The quality assurance program shall include at least an annual review of transfer cases, management of cases, and educational programs and protocols among facilities which transport **maternal and neonatal** to one another pursuant to collaboration/**transfer** agreements. (3) Outcome statistics including neonatal and perinatal mortality, as well as appropriateness of neonatal and maternal transfers, shall be compiled in a standardized manner and reviewed ~~periodically~~ **on a quarterly basis** by the	Clarification added

CURRENT REGULATION	PROPOSED CHANGES	RATIONALE FOR CHANGE
(4) The quality assurance program shall include an annual Hearing Screening Program Evaluation of critical performance data, including but not limited to, number of live births, number of infants screened, number of infants who passed the screening, number of infants who did not pass the screening in the right ear, number of infants who did not pass the screening in the left ear, number of infants who did not pass the screening in both ears, number of infants who missed screening or were unsuccessfully screened, the number of infants referred for diagnostic testing, and the number of parents or guardians who refused screening.	hospital perinatal committee. Neonatal and maternal deaths after transfer or discharge from the facility (within first 28 days of birth) shall be included in the statistics.	
(F) Nurse Staffing.		
(1) The nurse staffing pattern for the maternal-newborn service shall be planned, developed and budgeted (at least on an annualized basis) using data from a patient classification system acceptable to the Department. If a patient classification system is not used, nationally recognized staffing standards such as those outlined in the *Guidelines for Perinatal Care*, shall be applied to the facility's case-mix and volume to plan, develop and budget for the staffing pattern.	(1) The nurse staffing pattern for the maternal-newborn service, **consistent with the most current edition of the Guidelines for Perinatal Care,** shall be planned, developed and budgeted (at least on an annualized basis) ~~using data from a patient classification system acceptable to the Department~~ ~~If a patient classification system is not used, nationally recognized staffing standards such as those outlined in the *Guidelines for Perinatal Care*, shall be applied to the facility's case-mix and volume to plan, develop and budget for the staffing pattern.~~	Regulation strengthened by requiring compliance with staffing pattern recommended for quality care in the Guidelines for Perinatal Care.
(2) In addition, the Maternal-Newborn service shall meet the following requirements:		

CURRENT REGULATION	PROPOSED CHANGES	RATIONALE FOR CHANGE
(a) A registered nurse shall assess the needs, plan the care and evaluate the care delivery including the health education of each patient.		
(b) A registered nurse shall observe and care for the mother, fetus and newborn during the labor, delivery and recovery periods.		
(c) A registered nurse shall be present during the delivery. A second licensed nurse shall be immediately available as additional support until the mother and infant are stabilized.	(c) A registered nurse **who is certified in neonatal resuscitation by a recognized program, such as the Neonatal Resuscitation Program (NRP)** shall be present during the delivery. A second ~~licensed~~ **registered** nurse shall be immediately available as additional support until the mother and infant are stabilized.	The language is updated and strengthened to require certification in neonatal resuscitation skills training program.
(d) A registered nurse shall complete an initial newborn nursing assessment and shall be responsible for notifying the physician of any abnormalities or problems.		
(e) A registered nurse shall be on duty in each patient care unit on every shift.		
(f) A program of breastfeeding support for families and maternal- newborn staff shall be offered by competent staff and shall address the following areas:	~~(f) A program of breastfeeding support for families and maternal- newborn staff shall be offered by competent staff and shall address the following areas:~~	Requirements deleted here and all elements moved to separate section on Lactation Care and Services.
(i) The nutritional and physiological aspects of human lactation.	~~(i) The nutritional and physiological aspects of human lactation.~~	
(ii) Positioning of mother and infant to promote effective sucking, milk release and production.	~~(ii) Positioning of mother and infant to promote effective sucking, milk release and production~~	
(iii) Practices to avoid and treat common breastfeeding difficulties.	~~(iii) Practices to avoid and treat common breastfeeding difficulties.~~	
(iv) Nutritional needs of the mother during lactation.	~~(iv) Nutritional needs of the mother during lactation.~~	
(v) Safe techniques for milk expression and storage of breast milk.	~~(v) Safe techniques for milk expression and storage of breast milk.~~	
(vi) Information about community support services available to the family after discharge.	~~(vi) Information about community support services available to the family after discharge.~~	
(vii) Cultural values related to breastfeeding.	~~(vii) Cultural values related to breastfeeding.~~	

CURRENT REGULATION	PROPOSED CHANGES	RATIONALE FOR CHANGE
(g) All licensed nursing staff caring for maternal-newborn patients shall receive orientation and periodic inservice education that provides training or documents skill in at least the following areas:	(g) **The hospital shall ensure that a**ll licensed nursing staff caring for maternal-newborn patients **have demonstrated current competency in providing care in the specialty area. All licensed nursing staff** shall receive orientation and periodic in-service education **related to the current best practices for maternal and newborn care** ~~that provides~~ **including** training or ~~documents~~ **documented** skill in at least the following areas:	Section (g) is reorganized for clarity and language changes and additions are made to update the requirements
(i) Family-centered care.	~~(i) Family-centered care.~~	
(ii) Evaluation of the condition of the mother, fetus and newborn.	**(i)** ~~(ii)~~ Evaluation of the condition of the mother, fetus and newborn.	
(iii) Assessment of risk during the labor, delivery, recovery and postpartum periods.	**(ii)** ~~(iii)~~ Assessment of risk during the labor, delivery, recovery and postpartum periods.	
(iv) Use of electronic fetal monitor, interpretation of fetal heart-rate patterns and initiation of appropriate nursing interventions (for nurses caring for pregnant woman).	**(iii)** ~~(iv)~~ **Fetal assessment modalities including u**se of electronic fetal monitor, interpretation of fetal heart-rate patterns and initiation of appropriate nursing interventions **for non-reassuring patterns** (for nurses caring for pregnant woman).	
(v) Nursing management of emergency situations.	**(iv)** ~~(v)~~ Nursing management of emergency situations **that specifies communication and decision-making responsibilities and chain of command.**	
(vi) Adult and newborn resuscitation.	**(v)** ~~(vi)~~ Adult and newborn resuscitation.	
(vii) Immediate care and assessment of the newborn.	**(vi)** (~~vii~~) Immediate care and assessment of the newborn.	
	(vii) Family-centered care that is culturally and linguistically appropriate. **(viii) Support of the normal processes of labor and birth** **(ix) Mother and infant security**	
(viii) Initiation and support of lactation.	~~(viii)~~ **(x)** Initiation and support of lactation.	
(h) The licensed nursing staff shall receive documented annual retraining in cardio-pulmonary resuscitation and mock code drills. Each maternal-newborn service shall provide licensed nursing staff with continuing education in specialty areas of the service.	(h) The ~~licensed~~ nursing staff shall receive documented annual retraining in **adult and neonatal** cardio-pulmonary resuscitation and mock code drills. Each maternal-newborn service shall provide licensed nursing staff with continuing education in specialty areas of the service.	Language change for clarity
	(G) Lactation Care and Services	New section added to strengthen requirements for

CURRENT REGULATION	PROPOSED CHANGES	RATIONALE FOR CHANGE
	(1) Each hospital shall deliver lactation care and services by staff members with knowledge and experience in lactation management. At a minimum, each hospital shall provide every mother and infant requiring advanced lactation support with ongoing consultation during the hospital stay from an International Board Certified Lactation Consultant (IBCLC) or an individual with equivalent training and experience. **(2) Each maternal and newborn service shall develop written, evidence-based breastfeeding polices and procedures and include these in staff education and competency reviews.** **(3) An educational program of lactation support for maternal-newborn staff shall be offered by qualified staff and shall address the following areas:** **(a) The nutritional and physiological aspects of human lactation.** **(b) Positioning of mother and infant to promote effective sucking, milk release and production.** **(c) Practices to avoiding, recognizing and treating common breastfeeding ~~difficulties~~ complications** **(d) Nutritional needs of the mother during lactation.** **(e) Safe techniques for milk expression and storage of milk** **(f) Information about community support services available to the family after discharge** (g) **Cultural values related to breastfeeding**	breastfeeding support
130.617: Ancillary Services		
(A) Laboratory. The clinical laboratory services available for maternal and newborn patients shall be defined by the Chief of Laboratory Services in consultation with the Chief(s) of both Maternal and Newborn Services and the hospital administrator or his or her designee.		

CURRENT REGULATION	PROPOSED CHANGES	RATIONALE FOR CHANGE
(B) Radiology.		
(1) The Chief of Radiology shall define the diagnostic radiological procedures available for maternal and newborn patients in consultation with the Chief(s) of both the Maternal and Newborn Services and the hospital administrator or his or her designee.	(1) The diagnostic **imaging and** radiological procedures available for maternal and newborn patients shall be defined by the Chief of Radiology in consultation with the Chief(s) of both the Maternal and Newborn Services and the hospital administrator or his or her designee	Language change to update standards
(2) The maternal-newborn service shall have written policies for diagnostic radiologic examination of pregnant patients aimed at preventing excessive radiation exposure to the fetus and mother.		
(3) A written request for a diagnostic radiologic examination of a pregnant patient shall clearly indicate to the person taking the x-ray that the patient is pregnant.		
(4) Each radiologic service shall have an orientation and guidelines for personnel taking infant x-rays which address at a minimum safe positioning of the newborn, measures to minimize x-ray exposure and prevention of x-ray exposure to the infant's gonads.	4) Each radiologic service shall have an orientation **training program and protocols** ~~and guidelines~~ for personnel ~~taking~~ **performing** infant x-rays which address at a minimum safe positioning of the newborn, measures to minimize x-ray exposure and prevention of x-ray exposure to the infant's gonads.	Language change for clarification
130.618: Environment: General Requirements		
(A) New construction or alterations/additions to existing services shall meet applicable portions of the Department of Health and Human Services publication entitled: *Guidelines for Construction and Equipment for Hospital and Medical Facilities*.	(A) New construction or alterations/additions to existing services shall meet applicable portions of the Department of Health and Human Services **and the American Institute of Architects** publication entitled: *Guidelines for **Design and** Construction ~~and Equipment for~~ **of** Hospital**s** and ~~Medical~~ **Health Care** Facilities*.	Language change to update standards
(B) The maternal-newborn service shall be self-contained and discrete from other hospital services and be situated so as to accommodate patient flow without passing through other functional areas of the hospital. There shall be limited access to the service.		
(C) All equipment, furnishings and decorations in the maternal newborn service shall be made		

CURRENT REGULATION	PROPOSED CHANGES	RATIONALE FOR CHANGE
of washable materials.		
(D) The environment shall foster family-centered care including provisions for:		
(1) Mothers and infants to room-in together on a 24 hours a day basis.		
(2) Respect for the privacy of all mothers and families.		
(3) Visitation for father or significant other(s) on a 24 hours a day basis.		
(4) Accommodating visitors.		
(5) Private area for mothers to nurse and/or use breast pump.		
	(6) Rapid reunion of mother and infant after medical/surgical procedures, including cesarean section and circumcision.	Addition intended to strengthen opportunity for mother and infant bonding
(E) Maternal-newborn services shall have the capability to provide care during labor, delivery, recovery and post-partum periods. Maternal-newborn services may have any one or a combination of several functional configurations including labor-delivery suites, birthing rooms, combination labor- delivery-recovery rooms and labor-delivery-recovery-postpartum rooms. Sufficient equipment shall be available to accommodate rooms in the event of simultaneous use. Each facility shall have at least one delivery room equipped for cesarean births. Cesarean births shall be performed in this room.		
	(F) The maternal and newborn service shall have appropriate resources and facilities to care for antepartum patients requiring stabilization, hospitalization, or transfer for obstetrical conditions. **(G) Antepartum facilities shall be designed to ensure outpatient areas are separate from inpatient service areas.**	Addition recognizes need to address services delivered to antepartum patients.
130.619: Labor-Delivery Suite		
(A) Labor Room.		
(1) At least two labor beds shall be provided for each delivery room. (Birthing room; labor, delivery, recovery room; and labor, delivery, recovery and post-partum room beds may be substituted for labor beds.)		
(2) The labor room shall provide a minimum of ten square feet per bed except that	(2) The labor room shall provide a minimum of ~~ten~~ **120** square feet per bed	Updated to meet the current standards outlined in

CURRENT REGULATION	PROPOSED CHANGES	RATIONALE FOR CHANGE
maternal-newborn services in existence prior to July 3, 1989 shall provide at least 80 square feet per bed in multiple bed rooms.	except that maternal-newborn services in existence prior to ~~July 3,~~ ~~1989~~ **the promulgation of these regulations** shall provide at least ~~80~~ **100** square feet	Department of Health and Human Services and American Institute of Architects publication entitled: *Guidelines for Design and Construction of Hospitals and Health Care Facilities*
(3) Labor rooms shall not accommodate more than two mothers. Partitions or curtains shall be provided to insure privacy for multiple-occupancy rooms.		
(4) Labor rooms shall have the traditional hospital wall covering and furnishings or an attractive comfortable "homelike" family-centered decor.		
(5) The labor room shall contain or have access to toilet and shower facilities.		
(6) Each labor room shall contain the following:		
(a) Nurse call system.		
(b) Emergency call or intercommunication system.		
(c) Oxygen outlet(s).		
(d) Suction outlet(s).		
(e) Sphygmomanometer with adult stethoscopes.		
(f) Fetoscope or instrument for fetal auscultation.		
(g) Clock with sweep second hand.		
(h) Lighting for examinations.		
(i) Bed for each patient.		
(j) Seating for family members.		
(k) Functional source of emergency electrical power.		
(7) Each labor room shall have readily available:		
(a) Handwashing units with elbow, knee or foot controls.	(a) **Hands-free h**~~H~~handwashing units. ~~with elbow, knee or foot controls~~.	Language change to update
(b) Emergency delivery kit.		
© Resuscitation medications and equipment for both mother and infant.		
(d) Electronic fetal monitoring equipment.		
(8) All facilities, furnishings and equipment shall be washable.		
(9) The labor room shall have access to a delivery room for emergency cesarean birth management.		

CURRENT REGULATION	PROPOSED CHANGES	RATIONALE FOR CHANGE
	(10) The maternal newborn service shall designate adequate and appropriate space for labor triage.	Specific language addressing triage is added to ensure appropriate facilities are designated.
(B) Delivery/Cesarean Birth Room.	(B) ~~Delivery/Cesarean Birth Room.~~ **Cesarean/Delivery Room**	In this section (B) the name of the room type is changed to be consistent with the most current version of the *Guidelines for Design and Construction of Hospitals and Health Care Facilities* published by the Department of Health and Human Services and American Institute of Architects. Room size updated to meet the current standards outlined in Department of Health and Human Services and American Institute of Architects publication entitled: *Guidelines for Design and Construction of Hospitals and Health Care Facilities*
(1) The delivery/cesarean birth room shall meet the infection control standards of the hospital's operating rooms.	(1) The ~~delivery/cesarean~~ **cesarean/delivery room** ~~birth~~ room shall meet the infection control standards of the hospital's operating rooms.	
(2) Additional surgical procedures limited to pregnancy related conditions only, such as dilatation and currettage and postpartal tubal ligations, may be performed within the delivery/cesarean birth room.	(2) Additional surgical procedures limited to pregnancy related conditions only, such as dilatation and curettage and postpartum tubal ligations, may be performed within the ~~delivery/cesarean birth room~~**.cesarean/delivery room.**	
(3) Each delivery/cesarean birth room shall contain at least 360 square feet of space, except that such rooms that are not used for cesarean births may contain at least 300 square feet. Delivery rooms and cesarean birth rooms in existence prior to July 3, 1989 shall contain at least 324 square feet,	(3) Each ~~delivery/cesarean birth room~~ **cesarean/delivery room** shall contain at least ~~360~~ **400** square feet of space, except that such rooms that are not used for cesarean births may contain at least 300 square feet. Delivery rooms and cesarean/**delivery** ~~birth~~ rooms in existence prior to July 3, 1989 shall contain at least 324 square feet. M**aternal-newborn services in existence prior to the promulgation of these regulations but after July 3, 1989 shall provide at least 360 square feet**	
(4) Environmental requirements for the delivery/cesarean birth room shall include:	(4) Environmental requirements for the ~~delivery/cesarean birth~~ **cesarean/delivery** room shall include:	
(a) Adequate lighting for vaginal and cesarean births.		
(b) Temperature control to prevent chilling of mother and newborn.		
(c) Functional source of emergency electrical power.		
(d) Oxygen and suction outlets for both mother and newborn.		
(e) Emergency call system.		
(f) Scrub sinks withs, knee or foot controls in or adjacent to the room.	(f) **Hands-free s**crub ~~sinks with elbow, knee or foot controls~~ in or adjacent to the room.	
(g) Wall clock with sweep second hand.		
(h) Mirrors for mothers to observe births.		
(5) The delivery/cesarean birth room shall contain at least the following equipment:	(5) The ~~delivery/cesarean birth~~ **cesarean/delivery** room shall contain at least the following equipment:	

CURRENT REGULATION	PROPOSED CHANGES	RATIONALE FOR CHANGE
(a) Delivery bed permitting variation in position for birth as well as anesthesia administration.		
(b) Facilities for both regional and inhalation anesthesia.		
(c) Immediate availability of adult and newborn resuscitation equipment including the following:		
(i) Emergency medications.		
(ii) Airway and intubation instruments.		
(iii) Defibrillator.		
(iv) Cardiac monitor.		
(v) Oxygen administration equipment.	(v) Oxygen administration equipment **and oxygen saturation monitor.**	Updated to reflect current standards for equipment availability
(vi) Blood and intravenous administration sets.		
(d) Heated, temperature controlled neonatal examination and resuscitation bed.		
(e) Instruments for vaginal delivery, repair of lacerations, cesarean birth and management of obstetric emergencies.		
(f) Duplicate infant identification device.		
(g) Equipment for clamping of the umbilical cord.		
	(h) Blanket warmer **(i) Fluid warmer**	Updated to reflect current standards for equipment availability
(C) Additional Equipment and Facilities. The labor/delivery suite shall contain:		
(1) Access to radiologic viewboxes.	(1) Access to radiological viewboxes **or digital imaging.**	Updated to reflect current standards for equipment availability
(2) Access to stretcher with siderails.		
(3) Adequate clean storage and preparation area.		
(4) Access to high speed sterilization of equipment.	(4) **Ready** ~~A~~access to ~~high speed~~ sterilization ~~of equipment~~ **facilities.**	Updated to reflect current standards for equipment availability
(5) At least one utility room with adequate space and facilities for cleaning equipment.	(5) At least one ~~utility room~~ **soiled workroom** with adequate space and facilities for cleaning equipment.	Updated to clarify space needed to appropriately carry out required functions
(6) Sleeping, shower, locker, lounge and toilet facilities for staff, separate from patients' area.		
(7) Desk area.	~~(7) Desk area~~. **Documentation area for administrative functions.**	Updated to clarify space needed to appropriately

CURRENT REGULATION	PROPOSED CHANGES	RATIONALE FOR CHANGE
		carry out required functions
(8) Lounge accessible to patients and visitors.		
(D) Recovery Area.		
(1) Except for any maternal-newborn service which was in existence on July 3, 1989, each maternal-newborn service that has or exceeds 1500 births per year in the labor delivery suite shall provide a designated recovery area under registered nurse supervision.	(1~~) Except for any maternal-newborn service which was in existence on July 3, 1989, each maternal-newborn service that has or exceeds 1500 births per year in the labor delivery suite shall provide a designated recovery area under registered nurse supervision~~ Each maternal and newborn service which provides a separate recovery area that meet the following:	Recovery area requirements are reformatted.
(2) Hospital policy shall state the types of patient conditions requiring admission to the recovery area.	~~(2)~~ **(1)** Hospital policy shall state the types of patient conditions requiring admission to the recovery area.	Renumbered
(3) Each recovery area shall contain at least two bed and the following:	~~(3)~~ **(2)** Each recovery area shall contain at least two bed and the following:	Renumbered
(a) Suction and oxygen outlets for each bed.		
(b) Monitoring equipment appropriate to post anesthesia care.		
(4) Emergency medications and equipment shall be immediately accessible to the recovery area.	**(3)** Emergency medications and equipment shall be immediately accessible to the recovery area	
(5) During the recovery period the mother shall be under the direct observation of a licensed nurse.	**(4) The care of the mother and newborn d**uring the recovery period ~~the mother~~ shall be under the direct observation of a ~~licensed~~ **registered** nurse.	Language changed to reflect standard of care requiring oversight of care by a registered nurse.
(6) Provisions shall be made to maintain the family unit during the recovery period.	**(5)** Provisions shall be made to maintain the family unit during the recovery period.	
130.620: Birthing Room	130.620: Birthing Room	
	If the services include birthing room(s), the birthing room(s) shall meet all the requirements of a labor, delivery, recovery room (LDR) in 130.621.	Change made to eliminate the special category of 'birthing room'. The birthing room requirements are the same as for LDRs. Therefore a special category in the regulations is not necessary. The proposed change does not prohibit hospitals from using the term 'birthing room'

CURRENT REGULATION	PROPOSED CHANGES	RATIONALE FOR CHANGE
(A) There shall be written policies and procedures for the birthing room which shall include, at a minimum, provisions for the following:	~~(A) There shall be written policies and procedures for the birthing room which shall include, at a minimum, provisions for the following:~~	
(1) Admission criteria.	~~(1) Admission criteria.~~	
(2) Criteria for transfer to the delivery/cesarean birth room.	~~(2) Criteria for transfer to the delivery/cesarean birth room.~~	
(3) Restriction of anesthesia to local or pudendal block.	~~(3) Restriction of anesthesia to local or pudendal block.~~	
(4) Care of the normal newborn including length of stay in the birthing room.	~~(4) Care of the normal newborn including length of stay in the birthing room.~~	
(B) The birthing room may be located outside the labor-delivery suite but shall be within the maternity unit so that the patient may be transferred to the delivery/cesarean birth room without having to pass other functional areas of the hospital outside the maternity service.	~~(B) The birthing room may be located outside the labor-delivery suite but shall be within the maternity unit so that the patient may be transferred to the delivery/cesarean birth room without having to pass other functional areas of the hospital outside the maternity service.~~	
(C) Each birthing room shall contain a minimum of 200 square feet of floor space except that birthing rooms in existence, or for which plans have been approved by the Department prior to July 3, 1989 shall contain at least 160 square feet.	~~(C) Each birthing room shall contain a minimum of 200 square feet of floor space except that birthing rooms in existence, or for which plans have been approved by the Department prior to July 3, 1989 shall contain at least 160 square feet.~~	
(D) The birthing room shall have single patient occupancy.	~~(D) The birthing room shall have single patient occupancy.~~	
(E) The birthing room shall have a “homelike” family-centered decor.	~~(E) The birthing room shall have a “homelike” family-centered decor.~~	
(F) Each birthing room shall contain or have access to a toilet and shower or tub facility.	~~(F) Each birthing room shall contain or have access to a toilet and shower or tub facilities.~~	
(G) Each birthing room shall contain the following:	~~(G) Each birthing room shall contain the following:~~	
(1) Nurse call system.	~~(1) Nurse call system.~~	
(2) Emergency call or intercommunication system.	~~(2) Emergency call or intercommunication system.~~	
(3) Wall oxygen outlet.	~~(3) Wall oxygen outlet.~~	
(4) Wall suction outlet.	~~(4) Wall suction outlet.~~	
(5) Sphygmomanometer with adult stethoscopes.	~~(5) Sphygmomanometer with adult stethoscopes.~~	
(6) Fetoscope or a means of monitoring fetal heart rate.	~~(6) Fetoscope or a means of monitoring fetal heart rate.~~	
(7) Emergency delivery kit.	~~(7) Emergency delivery kit.~~	
(8) Clock with sweep second hand.	~~(8) Clock with sweep second hand.~~	
(9) Adjustable lighting adequate for examinations.	~~(9) Adjustable lighting adequate for examinations.~~	

CURRENT REGULATION	PROPOSED CHANGES	RATIONALE FOR CHANGE
(10) Bed.	~~(10) Bed.~~	
(11) Adequate seats for family members.	~~(11) Adequate seats for family members.~~	
(12) Functional source of emergency electric power.	~~(12) Functional source of emergency electric power.~~	
(H) (1) Each birthing room shall have readily available the following:	~~(H) (1) Each birthing room shall have readily available the following:~~	
(a) Handwashing unit with elbow, knee or foot controls.	~~(a) Handwashing unit with elbow, knee or foot controls.~~	
(b) Resuscitation medications and equipment for both mother and infant.	~~(b) Resuscitation medications and equipment for both mother and infant.~~	
(c) Electronic-fetal monitoring equipment.	~~(c) Electronic-fetal monitoring equipment.~~	
(d) Oxygen and suction capabilities for the infant.	~~(d) Oxygen and suction capabilities for the infant.~~	
(e) Bassinet.	~~(e) Bassinet.~~	
(f) Standard infant warming device.	~~(f) Standard infant warming device.~~	
(2) All equipment for labor, delivery and resuscitation may be portable but shall be present in the room at the time of delivery. All facilities, furnishing and equipment shall be washable.	~~(2) All equipment for labor, delivery and resuscitation may be portable but shall be present in the room at the time of delivery. All facilities, furnishing and equipment shall be washable.~~	
130.621: Labor-Delivery-Recovery Room.		
(A) There shall be written policies and procedures for the labor-delivery-recovery room which shall include, at a minimum, provisions for the following:		
(1) Admission criteria.		
(2) Criteria for transfer to the delivery/cesarean birth room.		
(3) Restriction of anesthesia to local or regional modes.		
(4) Care of the normal newborn including the minimum length of time the infant remains in the labor-delivery-recovery room.		
(B) The labor-delivery-recovery room may be located outside the labor-delivery suite but shall be within the maternity unit so the patient may be transfered to the delivery/cesarean birth room without having to pass through other functional areas of the hospital outside the maternity service.	(B) The labor-delivery-recovery room may be located outside the labor-delivery suite but shall be within the maternity unit so the patient may be transferred to the delivery/cesarean birth room without having to pass through other functional areas of the hospital outside the maternity service **and so that infant security is maintained.**	Language change to emphasize importance of infant security

CURRENT REGULATION	PROPOSED CHANGES	RATIONALE FOR CHANGE
(C) A minimum of 200 square feet of floor space shall be provided for each labor-delivery-recovery room.	(C) A minimum of ~~200~~ **250** square feet of floor space shall be provided for each labor-delivery-recovery room. . M**aternal-newborn services in existence prior to the promulgation of these regulations shall provide at least 200 square feet.**	Updated to meet the current standards outlined in Department of Health and Human Services and American Institute of Architects publication entitled: *Guidelines for Design and Construction of Hospitals and Health Care Facilities.*
(D) The labor-delivery-recovery room shall have single patient occupancy.		
(E) Each labor-delivery-recovery room shall contain or have access to toilet and shower or tub facilities.	(E) Each labor-delivery-recovery room shall contain or have access to **private** toilet and shower ~~or tub facilities.~~ **If tub facilities are provided, there shall be at least three feet clearance on two sides and end of the tub.**	Requirement related to clearance around tub added for safety to ensure that, in case of emergency, staff has access to the patient.
(F) Each labor-delivery-recovery room shall contain the following:		
(1) Nurse call system.		
(2) Emergency call or intercommunication system.		
(3) Oxygen outlet(s).		
(4) Suction outlet(s).		
(5) Sphygmomanometer with adult stethoscopes.		
(6) Continuous vital sign monitoring equipment for the mother (when regional anesthesia is used).		
(7) Equipment for the administration of local and regional anesthesia when these forms of anesthesia are indicated.		
(8) Fetoscope or a means of evaluating fetal heart rate.		
(9) Emergency delivery kit.		
(10) Clock with sweep second hand.		
(11) Adjustable lighting adequate for examinations.		
(12) Bed.		
(13) Adequate seating for family members.		

CURRENT REGULATION	PROPOSED CHANGES	RATIONALE FOR CHANGE
(14) Functional source of emergency electric power.		
(G) (1) Each labor-delivery-recovery room shall have readily available:		
(a) Handwashing unit with elbow, knee or foot controls.	(a) **Separate hands-free h~~H~~**handwashing unit. ~~with elbow, knee or foot controls.~~	Updated to meet the current standards outlined in Department of Health and Human Services and American Institute of Architects publication entitled: *Guidelines for Design and Construction of Hospitals and Health Care Facilities.*
(b) Resuscitation medications and equipment for both mother and infant.		
(c) Electronic fetal monitoring equipment.		
(d) Oxygen and suction capabilities for the infant.		
(e) Bassinet.		
(f) Standard infant warming device.		
(g) Equipment for the care of the newborn during the time period he/she remains in the labor-delivery-recovery room, as specified by hospital policy.		
	(h) Infant identification materials	Updated to clarify supplies required to appropriately carry out required functions.
(2) All equipment and medications for labor, delivery, anesthesia and resuscitation may be portable but shall be present in the room at the time of delivery.		
(H) All facilities, furnishings and equipment shall be washable.		
130.622: Labor Delivery-Recovery-Postpartum Room (Single Room Maternity Care)		
(A) There shall be written policies and procedures for the labor-delivery-recovery- postpartum room which shall include, at a minimum, provisions for the following:		
(1) Admission criteria.		
(2) Criteria for transfer to the delivery/cesarean birth room.		
(3) Restricton of anesthesia to local or regional modes.		

CURRENT REGULATION	PROPOSED CHANGES	RATIONALE FOR CHANGE
(B) The labor-delivery-recovery-postpartum room may be located outside the labor-delivery suite but shall be within the maternity unit so the patient may be transferred to the delivery/cesarean birth room without having to through other functional areas outside the maternity service.	(B) The labor-delivery-recovery-postpartum room may be located outside the labor-delivery suite but shall be within the maternity unit so the patient may be transferred to the delivery/cesarean birth room without having to through other functional areas outside the maternity service **and so that infant security is maintained.**	Language change to emphasis importance of infant security
(C) A minimum of 200 square feet of floor space shall be provided for each labor-delivery-recovery-postpartum room.	(C) A minimum of ~~200~~ **250** square feet of floor space shall be provided for each labor-delivery- recovery-postpartum room. **Except that labor-delivery-recovery-postpartum rooms in existence prior to the promulgation of these regulations shall provide a minimum of 200 square feet.**	Updated to meet the current standards outlined in Department of Health and Human Services and American Institute of Architects publication entitled: *Guidelines for Design and Construction of Hospitals and Health Care Facilities*
(D) The labor-delivery-recovery-postpartum room shall have single patient occupancy.		
(E) The labor-delivery-recovery-postpartum room shall have adequate soundproofing.		
(F) Each labor-delivery-recovery-postpartum room shall contain or have access to toilet and shower or tub facilities.	(F) Each labor-delivery-recovery-postpartum room shall contain or have access to **private** toilet and shower ~~or tub facilities.~~ **If tub facilities are provided, there shall be at least three feet clearance on two sides and end of the tub.**	Requirement related to clearance around tub added for safety to ensure that, in case of emergency, staff has access to the patient.
(G) Each labor-delivery-recovery-postpartum room shall contain the following:		
(1) Nurse call system.		
(2) Emergency call or intercommunication system.		
(3) Oxygen outlet.		
(4) Suction outlet.		
(5) Sphygmomanometer with adult stethoscope.		
(6) Continuous vital signs monitoring equipment for the mother (when regional anesthesia is		

CURRENT REGULATION	PROPOSED CHANGES	RATIONALE FOR CHANGE
used).		
(7) Equipment for the administration of local and regional anesthesia when these forms of anesthesia are indicated.		
(8) Fetoscope or a means of evaluating fetal heart rate.		
(9) Emergency delivery kit.		
(10) Clock with sweep second hand.		
(11) Adjustable lighting adequate for examinations.		
(12) Bed.		
(13) Adequate seating for family members.		
(14) Functional source of emergency electric power.		
(H) (1) Each labor-delivery-recovery-postpartum room shall have readily available:		
(a) Handwashing unit with elbow, knee or foot controls.	(a) **Separate hands-free h**~~H~~andwashing unit. ~~with elbow, knee or foot controls.~~	Updated to meet the current standards outlined in Department of Health and Human Services and American Institute of Architects publication entitled: *Guidelines for Design and Construction of Hospitals and Health Care Facilities*
(b) Resuscitation medications and equipment for both mother and infant.		
(c) Electronic-fetal monitoring equipment.		
(d) Oxygen and suction capabilities for the infant.		
(e) Bassinet.		
(f) Standard infant warming device.		
(g) Equipment for the care of the mother and normal newborn until discharge.		
	(h) Infant identification materials	Updated to reflect current standards for equipment availability to carry out required function
(2) All equipment for labor, delivery, anesthesia and resuscitation may be portable but shall be present in the room at the time of delivery.		

CURRENT REGULATION	PROPOSED CHANGES	RATIONALE FOR CHANGE
(I) All facilities, furnishings and equipment shall be washable.		
130.623: Postpartum Unit		
(A) Provisions shall be made to accommodate the mother and infant in the same room on a 24 hours a day basis as requested by the mother.		
(B) Equipment for each room in the postpartum unit shall include at least the following:		
(1) Suction and oxygen capabilities.		
(2) Availability of resuscitation equipment and emergency medications for both the mother and infant.		
(3) Sink with elbow, knee or foot controls in or adjacent to the room.	(3) **Hands-free s**ink ~~with elbow, knee or foot controls~~ in or adjacent to the room.	Updated to meet the current standards outlined in Department of Health and Human Services and American Institute of Architects publication entitled: *Guidelines for Design and Construction of Hospitals and Health Care Facilities*
(4) Available toilet and shower facilities.	(4) Available toilet **with sink** and shower facilities.	Updated to reflect current standards for equipment availability to carry out proper infection control protocols.
	(5) Staff emergency call system	Updated to meet the current standards outlined in Department of Health and Human Services and American Institute of Architects publication entitled: *Guidelines for Design and Construction of Hospitals and Health Care Facilities*
	(C) The hospital shall provide a minimum 124 square feet in multiple bedrooms and 144 square feet in single bedrooms.	Minimum square footage requirements added to ensure adequate space is provided in mother's room to accommodate an infant bassinet.
130.624: Nursery		

CURRENT REGULATION	PROPOSED CHANGES	RATIONALE FOR CHANGE
(A) Each service shall provide within its nurseries a minimum number of well infant bassinets that equals the number of maternity beds plus one bassinet per well infant nursery to accommodate at-home and enroute births, multiple births, retrotransfers and recovery infants.		
	(1) A lower number of bassinets may be acceptable, if the licensee demonstrates, through a statistical formula provided by the Department that a 95% probability is achieved for the availability of bassinets, based on the projected number of births per year and the average length of stay.	Inclusion of the method currently in use by the Department of Pubic Health to establish required number of bassinets.
(B) All newborns in the nursery shall at all times be in direct view of personnel accountable for them.		
(C) In the normal newborn nursery, each bassinet shall have an average of 24 square feet of floor space with a three foot distance between bassinets. Each bassinet shall be immediately accessible to the aisle.	(C) In the normal newborn nursery, each bassinet shall have an average of 24 square feet of floor space with a three foot distance **maintained** between bassinets. Each bassinet shall be immediately accessible to the aisle. **Bassinets shall not display cards with formula company names or logos.**	Addition intended to minimize formula advertising and enhance support of breastfeeding practices.
(D) The environment of the nursery shall provide:		
(1) Adequate illumination with a system of variation of light intensities.		
(2) Temperature of 75 to 80□F controlled by heating and air conditioning equipment.	(2) Temperature of ~~75 to 80F~~ **72 to 78 F** controlled by heating and air conditioning equipment.	Updated to meet the current standards outlined in Department of Health and Human Services and American Institute of Architects publication entitled: *Guidelines for Design and Construction of Hospitals and Health Care Facilities*
(3) Humidity of 40-60% with regularly scheduled monitoring.	(3) Humidity of ~~40-60%~~ **30-60%** with regularly scheduled monitoring.	Updated to meet the current standards outlined in Department of Health and Human Services and American Institute of Architects publication entitled: *Guidelines for Design and Construction of Hospitals and Health Care Facilities*
(4) Interior finish of off-white or colors which permit detection of cyanosis and jaundice.		

CURRENT REGULATION	PROPOSED CHANGES	RATIONALE FOR CHANGE
(5) Windows, if provided, shall have clear glass and doublepane insulation. Window coverings shall be fire-proof and easy to clean.		
	(6) Floor finishes shall be washable.	Updated to meet the current standards outlined in Department of Health and Human Services and American Institute of Architects publication entitled: *Guidelines for Design and Construction of Hospitals and Health Care Facilities*
(E) Nurseries shall be arranged so that entrance is gained solely through a well-lighted anteroom which shall make provision for a handwashing and gowning area.	(E) ~~Nurseries shall be arranged so that entrance is gained solely through a well-lighted anteroom which shall make provision for a handwashing and gowning area~~ **Well infant nurseries are designed to ensure restricted, secure access. Special care nurseries shall be arranged so that entrance is gained solely through a well-lighted anteroom which shall make provision for a handwashing and gowning area.**	Language is changed to clarify the intent of the well infant nursery design.
(F) At least one sink with elbow, knee or foot controls shall be provided for every eight bassinets.	(F) At least one **hands-free** sink ~~with elbow, knee or foot controls~~ shall be provided for every ~~eight~~ **six** bassinets.	Updated to meet the current standards outlined in Department of Health and Human Services and American Institute of Architects publication entitled: *Guidelines for Design and Construction of Hospitals and Health Care Facilities*.
(G) Adequate space shall be available to store various brands of and types of commercially prepared formulas.	(G) ~~Adequate space shall be available to store various brands of and types of commercially prepared formulas.~~ **Provision for the appropriate storage of minimum daily quantities of infant care supplies. All formula shall be safely stored behind closed doors and not visible.**	Language change for clarity. Requirement for closed door storage of formula adds another level of security
(H) Nursery equipment shall include at least the following:		
(1) Individual bassinets capable of storing individual supplies of linen and infant care equipment.		
(2) Suction, oxygen and compressed air.		

CURRENT REGULATION	PROPOSED CHANGES	RATIONALE FOR CHANGE
(3) Washable infant scales.		
(4) Covered receptacles for the disposal of soiled linen, diapers or waste, with removable linings or bags and with foot controls.		
	(5) Blanket warmer **(6) Staff emergency call system**	Updated to reflect current standards for equipment availability to carry out required functions
(I) The following shall be readily available to the nursery:		
(1) Emergency equipment and medications for infant resuscitation and stabilization prior to transfer.		
(2) Oxygen administration capabilities with humidification, blending device and analyzer.	(2) Oxygen administration capabilities with humidification, blending device and analyzer**; and oxygen saturation monitor.**	Adds equipment necessary for patient care
(3) Cardio-respiratory monitor with high/low alarm.		
(4) Commercially manufactured isolette with air filter or a radiant heat bed.		
(5) Refrigerator and freezer for storage of breast milk.		
(6) Electric breast pump.	(6) Electric breast pump **and collection kits.**	Adds equipment necessary for patient care
(7) Circumcision equipment.	(7) **Appropriate facilities and necessary equipment for circumcision**	Addition recognizes need for appropriate work space to perform the procedure
	(8) Hearing screening equipment.	Adds equipment necessary for patient care
130.625: Additional Physical Plant Requirements		
(A) Electric outlets shall have a common ground.		
(B) Electrical equipment shall be checked for current leakage and grounding adequacy when first introduced and at periodic intervals thereafter, per hospital equipment maintenance policy.		
(C) Plugs shall be hospital grade. Adaptors, extension cords and junction boxes shall not be used.		
(D) Emergency electrical power shall be available in all areas serving mothers and newborns,		

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including sufficient numbers of emergency electrical outlets to maintain life support systems.		
130.626: Infection Control		
(A) Each maternal-newborn service shall have policies and procedures requiring handwashing both on arrival in the unit as well as before and after each patient contact.	~~(A) Each maternal-newborn service shall have policies and procedures requiring handwashing both on arrival in the unit as well as before and after each patient contact.~~	This item incorporated into section (B) below.
(B) Each maternal-newborn service shall develop a policy for the management of infectious diseases which requires blood and body fluid precautions as currently defined by the U.S. Department of Health and Human Services Centers for Disease Control.	(B) ~~Each maternal-newborn service shall develop a policy for the management of infectious diseases which requires blood and body fluid precautions as currently defined by the U.S. Department of Health and Human Services Centers for Disease Control~~ **(A) Each maternal-newborn unit shall have policies incorporating standard precautions as defined by the most recent edition of the Centers for Disease Control and Prevention guidelines.** **(B) Policies and procedures shall include a requirement for staff hand hygiene on arrival in the unit as well as before and after each patient contact.**	This section is updated to reflect references to current infection control recommendations of the Centers for Disease Control and Prevention (CDC).
(C) Specific isolation precautions for other than blood-borne diseases shall be determined by the suspected or known pathogen and its mode of transmission. The facility's infection control policies shall incorporate the isolation categories outlined in the current edition of *Centers for Disease Control Isolation Precautions in Hospitals*.	~~(C) Specific isolation precautions for other than blood-borne diseases shall be determined by the suspected or known pathogen and its mode of transmission. The facility's infection control policies shall incorporate the isolation categories outlined in the current edition of *Centers for Disease Control Isolation Precautions in Hospitals.*~~ **(C) Infection specific precautions shall be based on the identified or suspected pathogen and it's known mode of transmission and shall be applied in accordance with the most recent edition of the Centers for Disease Control and Prevention guidelines.**	

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(D) (1) The maternal-newborn service shall have a plan to manage the mother and/or the infant requiring physical isolation. Mothers and infants may be placed in isolation together on a 24 hours a day basis.		
(2) (a) The hospital shall define those infections for which separate isolation is required.		
However, if separate isolation is not provided, the following conditions shall be met:		
(i) An adequate number of nursing and medical personnel are on duty and have sufficient time for handwashing.	(i) An adequate number of nursing and medical personnel are on duty and have sufficient time for ~~handwashing~~ **hand hygiene.**	Language change to reflect current language of CDC
(ii) Sufficient space is available for a four - six foot aisle or area between newborn stations.		
(iii) An adequate number of sinks for handwashing are available and conveniently located to the "isolated" patient in each nursery room or area.		
(iv) Continuing instruction is given to personnel about the mode of transmission of infections.		
(b) When the criteria specified in 105 CMR 130.626(D)(2)(a) are not met or the physician determines separation of the infant is indicated, a separate nursery with handwashing facilities shall be used to house the infant.		
(3) Forced air incubators may be used for limited protective or reverse isolation of newborns and infants, *i.e.*, to protect these infants from others who may be infectious. Forced air incubators shall not be relied on as a means of preventing transmission from infected incubator patients to others.		
(E) The hospital policy shall establish maternal-newborn service staff dress requirements. At a minimum such policy shall include:		
(1) Provision for a clean barrier at the point of infant-caregiver contact.		
(2) Requirements for when cover gowns should be used.		
(3) A requirement that the hair of personnel shall be restrained in a manner that prevents its coming in contact with the patient.		
	(4) Staff shall not wear nametags, stethoscope tags etc. with the name or logo of any formula company.	Addition intended to minimize formula advertising and enhance support of breastfeeding practices.

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(F) Personnel assigned to maternal-newborn areas shall have:		
(1) Demonstrated immunity to rubella either via rubella titer or physician-documented rubella vaccine received on or after 12 months of age.		
(2) Demonstrated immunity to measles (rubeola) either via measles titer, physician- diagnosed disease or physician-documented live measles vaccine received on or after 12 months of age.		
(3) Tuberculin skin testing, repeat skin testing, and x-ray follow-up of staff with positive findings as defined by hospital infection control policy. At a minimum staff shall be tested at time of hiring, unless a previously significant reaction can be documented.		
(F) Exclusion of personnel with communicable diseases shall be defined by hospital policy and consistent with the current 105 CMR 300.000: *Reportable Diseases and Isolation and Quarantine Requirements*.	~~(F)~~ **(G)** Exclusion of personnel with communicable diseases shall be defined by hospital policy and consistent with the current 105 CMR 300.000: *Reportable Diseases **Surveillance** and Isolation and Quarantine Requirements*	Update reference
(G) Policies and procedures for cleaning, disinfection or sterilization of patient care areas, equipment, supplies and infant linen shall be established, approved and periodically reviewed by the hospital's infection control officer or equivalent.	~~(G)~~ **(H)** Policies and procedures for cleaning, **disinfecting** or sterilization of patient care areas, equipment, supplies and infant linen shall be established, approved and periodically reviewed by the hospital's infection control officer or equivalent.	Minor language change
130.627: Records		
(A) Maternal Record. The obstetrics service shall establish and maintain a system for obtaining prenatal records or summaries of records of patients during the last trimester of pregnancy and for making them available to the staff of the labor and delivery unit when the patient is admitted for delivery.	(A) Maternal Record. The obstetrics service shall establish and maintain a system for obtaining prenatal records or summaries of records of patients ~~during the last trimester~~ **at 24 weeks** of pregnancy and for making them available to the staff of the labor and delivery unit when the patient is admitted for delivery. **Such records shall be maintained as part of the mother's permanent record.**	Revised to better ensure records are available in case of pre-term delivery.
In addition to the requirements for all hospital patient records, the mother's record shall include:		
(1) Mother's medical and obstetric history including prenatal course.		

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(2) Antenatal blood serology, Rh factor, blood type, and HBsAg test results.	(2) Antenatal blood serology, Rh factor, blood type, ~~and~~ HBsAg test, **rubella antibody and Group B streptococcal culture** results. **In addition, results of maternal HIV testing, if done.**	Requirements updated
(3) Admission obstetrical examination including the condition of both mother and fetus.		
(4) Complete description of progress of labor and delivery, signed by the attending physician, or certified nurse midwife, including reasons for induction and operative procedures.		
(5) Type of medications, analgesia and anesthesia administered to the patient during labor and delivery.		
(6) Signed report of qualified obstetric or other consultant when such service has been obtained.		
(7) Names and credentials of all those present during delivery.		
(8) Description of postpartal course, including complications and treatments, signed by the attending physician or certified nurse midwife.		
(9) Medications, including contraceptives, prescribed at discharge.		
(10) Infant's condition at birth including gestational age, weight, Apgar, blood type, and results of initial physical assessment.		
(11) Nursing assessment, diagnosis, interventions and teaching.		
(12) Method of infant feeding: progress and plans for further support of lactation or suppression of lactation.	(12) Method of infant feeding~~: progress and plans for further support of lactation or suppression of lactation~~.a**nd infant feeding plan of care and progress. Documentation of lactation care and services provided.**	Language change to require feeding plan of care for all feeding methods
(13) If neonatal death occurs, cause of death, assessment of the families coping mechanisms and plans for follow-up and/or referral of the family.		
(B) Newborn Record. In addition to the requirements for all patient records, the newborn record shall include:		
(1) Significant maternal diseases.		
(2) Mother's obstetric history including estimated date of confinement and prenatal care course.		
(3) Maternal antenatal blood serology, typing, Rh factors, rubella antibody titer, coombs test for maternal antibodies if indicated, and prenatal HBsAg test results.		
(4) Results of any significant prenatal diagnostic procedures including genetic testing and/or chromosomal analysis.		

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(5) Complications of pregnancy or delivery.		
(6) Duration of ruptured membranes.		
(7) Medications, analgesic and/or anesthesia administered to the mother.		
(8) Complete description of progress of labor including diagnostic tests, treatment rendered and reasons for induction or operative procedures.		
(9) Date and time of birth.		
(10) Cause of death if it occurs.		
(11) Condition of the infant at birth including Apgar score, resuscitation, time of sustained respirations, description of congenital anomalies, gestational age, head circumference, length, weight, pathological conditions and treatments.		
(12) Number of cord vessels and description of any placental anomalies.		
(13) Written verification of eye prophylaxis and mandated screening tests, including time and date.	(13) Written verification of eye prophylaxis**, vitamin K** and mandated screening tests, including time and date	Updated
(14) Method of feeding.	(14**) (i)** Method of feeding **and feeding plan of care.** **(14) (ii) Documentation of at least two successful feedings, for both breastfeeding and formula fed infants.**	Addition broadens requirements to ensure feeding plan of care for all feeding methods. Documentation supports recommendation of the Academy of Pediatrics' policy statement for the hospital stay of healthy term newborns.
(15) Report of infant's initial medical examination within 24 hours of birth, signed by the infant's attending physician or his/her physician designee.		
(16) Informed consent for circumcision or any other surgical procedures.		
(17) Physician progress notes written in accordance with hospital policy.		
(18) A report of discharge examination signed by attending physician, certified nurse midwife or pediatric nurse practitioner within 24 hours of discharge.		
(19) Nursing assessment, diagnosis, interventions and teaching.		
(20) Documentation that hearing screening has been performed, screening results and referral, if any.	(20) Documentation that hearing screening has been performed, screening results and referral, if any. **If a referral is made, the medical record should document the date, time and location of the follow-up appointment.**	Addition intended to better ensure necessary follow-up care is documented.

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	(21) Discharge instruction sheet including feeding plan, referrals and follow-up care signed by the infant's practitioner.	Updated to reflect current standard of practice.
130.628: Data Collection and Reporting Systems		
(A) Each maternal-newborn service shall develop policies and procedures consistent with Massachusetts General Laws related to maternal and newborn care.		
(B) Each maternal-newborn service shall maintain a daily patient care log which documents the information required by the Massachusetts Department of Public Health, Division of Health Statistics and Research annual report.		
© The death of a pregnant woman during any stage of gestation, labor or delivery or the death of a woman within 90 days of delivery or termination of pregnancy shall be reported within 48 hours to the Department by the hospital in which the death occurs.		
	(D) Each hospital with a maternal-newborn service and a pediatric hospital with a neonatology subspecialty service shall submit patient-specific data reports that include practice benchmarks such as transfers, retro-transfers, and maternal and newborn medical conditions to the Massachusetts Department of Public Health in accordance with Department guidelines.	Consistent with the Department's continuing efforts to reduce maternal and infant mortality and morbidity, this new reporting requirement will enhance the Department's efforts to monitor outcomes and identify problems. The Department will work with the Perinatal Advisory Committee to establish required data reporting elements consistent with patient confidentiality standards.
130.629: Universal Newborn Hearing Screening Programs		
(A) Definitions.		
Audiologist shall mean an audiologist licensed by the Commonwealth of Massachusetts pursuant to the Board of Registration of Speech-Language Pathology and Audiology regulations		

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at 260 CMR 1.00 *et seq*., who meets such requirements for additional experience as defined by the Department in the Universal Newborn Hearing Screening Guidelines.		
Birth center shall mean either a free-standing or hospital-affiliated birth center, as defined at 105 CMR 142.000 *et seq*..		
Birth hospital shall mean, for the purposes of regulations regarding universal newborn hearing screening programs in 105 CMR 130.000 *et seq*. and 105 CMR 142.000 *et seq*., a hospital with a maternal and newborn service, as designated by the Department pursuant to 105 CMR 130.600 et seq., or a hospital without a maternal and newborn service but with a pediatric service, as designated by the Department pursuant to 105 CMR 130.700 *et seq*., from which an infant may be initially discharged to home.		
Hearing screening shall mean a test to detect hearing thresholds of 30 decibels or greater in either ear in the speech frequency range. The methodology shall be one that is defined as acceptable by the American Academy of Pediatrics and the American Speech and Hearing Association for the purposes of newborn infant hearing screening. The hospital's or birth center's screening outcomes shall meet referral rates established by the Department in the Universal Newborn Hearing Screening Guidelines.		
Newborn infant shall mean, for the purposes of regulations regarding universal newborn hearing screening programs in 105 CMR 130.000 *et seq*. and 105 CMR 142.000 *et seq*., an infant less than three months of age.		
(B) Information and Screening Requirements.		
(1) Prior to the hearing screening of a newborn infant, the hospital or birth center shall include information explaining the importance of newborn hearing screening and follow-up in materials distributed to parents or guardians.		
(a) This information shall be readily available in the languages of any non-English speaking	(a) This information shall be readily available in the ~~languages of any non-~~	Updated language

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group which comprises at least 10% of the birth hospital or birth center's obstetrical services population.	~~English speaking group which comprises at least 10% of the birth hospital or birth center's obstetrical services population.~~ the **major languages as identified through the acute hospital's language needs assessment required under 105CMR 130.1103 (A) and literacy levels** of the population served by the maternal-newborn service.	
(b) Translation of the information to languages used by a smaller percentage of the obstetrical population shall be provided prior to the hearing screening to the maximum extent possible, but in no event later than discharge.		
(c) For a hospital without a maternal newborn service from which a newborn infant may be initially discharged to home, the hospital shall ensure that translation of the hearing screening information is provided to non-English speaking parents or guardians of a newborn infant prior to discharge to the maximum extent possible.		
(2) Each birth hospital and birth center shall ensure that a hearing screening is performed on all newborn infants before the newborn infant is initially discharged to home.		
(a) If a newborn infant is transferred directly from the birth hospital or birth center to another hospital, the responsibility for screening lies with the hospital from which the infant is initially discharged to home.		
(b) By the age of three months, an infant shall receive hearing screening. If an infant cannot be screened by the age of three months due to delayed physiological development or physiological instability as a result of illness or premature birth, the infant shall be screened prior to discharge and as early as physiological development or stability will permit reliable screening.		
(3) Such screening shall not be performed if the parent or guardian of the newborn infant objects to the screening based upon sincerely held religious beliefs.		
(4) If an infant is not successfully screened or missed a screening prior to discharge, the birth hospital or birth center shall contact a Department approved screening center to make an appointment for a screening.		
(5) The birth hospital or birth center shall inform, orally and in writing, a parent or guardian of the newborn infant if the infant was not successfully screened or missed a screening. This information shall also be provided in writing to the newborn infant's primary care physician and		

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the Department through its electronic birth certificate system or such mechanism as specified by the Department.		
(a) Such notice shall occur prior to discharge whenever possible, but in any case no later than ten days following discharge.		
(b) The birth hospital or birth center so informing the parent or guardian and physician shall provide written information to the parent or guardian and physician regarding appropriate follow-up for an infant who missed a screening or was not successfully screened. This information shall include at a minimum the time and location of the screening appointment that has been scheduled, the telephone number of the screening site, a list of diagnostic test centers approved by the Department, as well as information about the importance of screening and follow-up. The information shall be provided to the parent or guardian in writing in the language understood by the parent or guardian.		
(6) If an infant did not pass the hearing screening, the birth hospital or birth center shall contact a Department approved diagnostic test center to make an appointment for a diagnostic test.		
(7) The birth hospital or birth center shall inform, orally and in writing, a parent or guardian of the newborn infant if the infant did not pass the screening. This information shall also be provided in writing to the newborn infant's primary care physician as well as to the Department through its electronic birth certificate system or such mechanism as specified by the Department.		
(a) Such notice shall occur prior to discharge whenever possible, but in any case no later than ten days following discharge.		
(b) The birth hospital or birth center so informing the parent or guardian and physician shall provide written information to the parent or guardian and physician regarding appropriate follow-up for an infant who did not pass the screening. This information shall include at a minimum the time and location of the diagnostic test appointment that has been scheduled, the telephone number of the diagnostic test site, a list of diagnostic test centers approved by the Department, as well as information about the importance of follow-up. The information shall be provided to the parent or guardian in writing in the language understood by the parent or guardian.		
(c) Screening Protocols.		

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(1) The birth hospital or birth center shall designate a program director who is responsible for the provision of newborn infant hearing screening services. The program director shall be an audiologist, neonatologist, pediatric otolaryngologist, neonatal or perinatal nurse, or pediatrician. The program director may delegate duties related to the oversight of the hearing screening service to appropriately trained staff.		
(2) A licensed audiologist shall oversee the provision of screening services and shall train the persons performing the screening.		
(3) Within 120 days of the effective date of 105 CMR 130.629, each birth hospital and birth center shall submit to the Department for its approval a protocol for newborn hearing screening. The protocol shall, at a minimum, to the satisfaction of the Department:		
(a) Identify the staffing of the program and outline the responsibilities of each staff member;		
(b) Describe the training and supervision of screening personnel by a licensed audiologist;		
(c) Identify the screening methods and equipment to be used to conduct the screening, including provisions for readily available back-up equipment in the event of an equipment malfunction;		
(d) Outline infection control procedures;		
(e) Provide samples of information to be provided to parents/guardians regarding the screening, including but not limited to information about coverage of the costs of the screening by third party payers, the potential risks of hearing loss, and the benefits of early detection and intervention;		
(f) Outline the procedure for documenting the results of the screening;		
(g) Identify the procedure for communicating that the infant did not pass, was unsuccessfully screened or missed the screening to the parent or guardian, primary care physician, and the Department. See 105 CMR 130.629(B)(5) and (B)(7);		
(h) Describe the training and supervision of individuals with responsibility to inform parents or guardians of screening results;		
(i) Identify the procedure to ensure an infant who missed a screening or was unsuccessfully screened will receive a screening. See 105 CMR 130.629(B)(4) and (B)(5);		
(j) Identify the procedure to ensure the parent or guardian of an infant who did not pass the screening will receive information about follow-up and an appointment for diagnostic services.		

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See 105 CMR 130.629(B)(6) and (B)(7);		
(k) Identify the procedure for reporting data on an annual basis or as otherwise required by the Department, including but not limited to, number of live births, number of infants screened, number of infants who passed the screening, number of infants who did not pass the screening in the right ear, number of infants who did not pass the screening in the left ear, number of infants who did not pass the screening in both ears, number of infants who missed screening or were unsuccessfully screened, the number of infants referred for diagnostic testing, and the number of parents or guardians who refused screening;		
(l) Describe the screening program's Quality Assurance review process; and		
(m) Include a provision for the review of hearing screening status in the discharge plan for all newborn infants required at 105 CMR 130.630(E)(2)(e), 130.640(B)(4)(p), 130.650(B)(4)(i), and 130.663 and in the information concerning the condition at discharge or transfer required at 105 CMR 142.504(D)(7).		
(4) Prior to implementing a significant change in a hearing screening protocol approved by the Department, a hospital or birth center must request and have received written approval of the change from the Department.		
130.630: Level I - Community-Based Maternal-Newborn Service		
The Level I Service shall meet all of the General Requirements for Maternal-Newborn Services contained in 105 CMR 130.600 through 130.628 and, in addition, the following:	**The Level I service capabilities include the management of uncomplicated pregnancies and the management of pregnancy complications not requiring the facilities and resources of Level 1B, II A, II B or level III services. Provides for the care and management of well newborns, stable infants born at ≥ 35 weeks gestation, including stable retro-transferred infants not needing Level I B, II A, II B or III services.** The Level I Service shall meet all of the General Requirements for Maternal-Newborn Services contained in 105 CMR 130.600 through 130.628 and, in addition, the following:	
(A) Collaboration Agreements. The Level I service shall establish formal written collaboration	(A) Collaboration/**Transfer** Agreements. The Level I service shall	Addition of transfer component corresponds to

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agreements with at least one Level II and one Level III hospital within geographic proximity.	establish formal written collaboration/**transfer** agreements with at least one ~~Level II and one~~ Level III hospital within geographic proximity **and other hospitals to which the service regularly refers patients.**	additions made to collaboration/transfer agreement requirements in 130.616 (B). Agreement with a Level II facility would only be required if the Level I facility regularly transferred patients to that facility.
(B) Administration and Staffing.		
(1) An obstetrician either certified or eligible for certification by the American Board of Obstetrics and Gynecology shall be designated as medical director of the maternal service.	(1) An obstetrician either certified or ~~eligible for certification~~ **an active candidate for** certification by the American Board of Obstetrics and Gynecology shall be designated as medical director of the maternal service.	Language updated.
(2) A pediatrician either certified or eligible for certification by the American Board of Pediatrics shall be designated as medical director of the newborn service.	(2) A pediatrician either certified or ~~eligible~~ **an active candidate for** certification by the American Board of Pediatrics **and experienced in the care of newborns** shall be designated as medical director of the newborn service. **The medical director or his/her designee shall be available on-call 24 hours a day.**	Language adds requirement for management coverage 24 hours a day.
(3) The medical directors of the maternal service and the newborn service shall collaborate in the overall medical management of the maternal-newborn service.		
(4) An obstetrician either certified or eligible for certification by the American Board of Obstetrics and Gynecology shall be available on-call on a 24 hours a day basis.	(4) An obstetrician either certified or **an active candidate** for certification by the American Board of Obstetrics and Gynecology **with full privileges** shall be available on-call on a 24 hours a day basis.	Language updated and addition related to hospital privileges recognizes the hospital 's responsibility to determine qualifications necessary for practice.
(5) A pediatrician either certified or eligible for certification by the American Board of Pediatrics with newborn privileges shall be available on-call on a 24 hours a day basis.	(5) A pediatrician either certified or ~~eligible~~ **an active candidate** for certification by the American Board of Pediatrics with newborn privileges **or board certified or an active candidate for certification by the American Board of Family Practice with newborn privileges** shall be available on-call on a 24 hours a day basis.	Addition recognizes opportunity for director of the service and hospital to use appropriately qualified family practitioners to provide coverage.

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(6) The facility shall designate a nurse who has responsibility and accountability for the 24 hour nursing management of the service. At a minimum, such nurse shall be a registered nurse with two years of experience in maternal-newborn nursing. In addition, she or he shall meet the qualifications for the management position as defined by hospital policy.	**(6) A registered nurse designated by the hospital shall be accountable for the 24 hour nursing management of the Level I nursery. At a minimum, this nurse shall be baccalaureate prepared (master's preferred) and have at least 2 years experience in the care of stable newborns.** **(7) A registered nurse educator, prepared at the baccalaureate level, shall have dedicated responsibility for coordinating and providing educational and training activities to enhance staff knowledge of relevant procedures and technological advances for staff of the maternal and newborn service.**	Defines nursing credentials that are consistent with nursing standards of practice. Addition of the requirement for a qualified nurse educator recognizes the role of the hospital to support maternal and newborn staff in maintaining and updating the necessary education and skill training to provide quality care.
(C) Services. The Level I Maternal-Newborn Service shall provide the following:	(C) Services. The Level I Maternal-Newborn Service shall provide the following **services**:	
(1) Social risk assessment and social work services. These services may be provided by the hospital social service department or through written arrangements with public or private social service agencies.	(1) Social risk assessment and social work services **by a licensed social worker(s) with experience in social assessment of high risk perinatal patients (mother/infant dyad), patient education, discharge planning, community follow-up programs, referrals and home care arrangements.** These services may be provided by the hospital social service department or through written arrangements with public or private social service agencies.	The addition strengthens the service requirements to better ensure a qualified individual provides the services.
(2) Nutritional consultation by a registered dietician experienced in maternal-newborn nutritional needs.	(2) Nutritional consultation by a ~~registered~~ dietician **registered by the American Dietetic Association and** experienced in maternal-newborn nutritional needs **available 7 days a week.**	Ensures availability of services when needed
(3) Medical risk assessment and early identification of high risk maternal, fetal and-newborn patients.	(3) Medical risk assessment and early identification of high-risk maternal, fetal and-newborn patients**, including access to or consultation with subspecialty services 24 hours a day.**	
(4) In the event of the need for emergency resuscitation and/or stabilization of the mother, an obstetrician shall be either onsite or called to come in to manage the emergency prior to transport	(4) **Emergency management of maternal patients, including the capacity to resuscitate and stabilize the patient prior to transfer.** In the event of	Additional language emphasizes and clarifies he requirement

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of the mother to a Level II or Level III service.	the need for emergency resuscitation and/or stabilization of the mother, an obstetrician shall be either onsite or called to come in to manage the emergency prior to transport of the mother to a Level II or Level III service.	
(5) In the event of the need for emergency resuscitation and/or stabilization of the infant a pediatrician shall be either onsite or called to come in to manage the emergency prior to transport of the infant to a Level II or level III service.	(5) **Emergency management of neonates, including the capacity to resuscitate and stabilize the patient prior to transfer.** In the event of the need for emergency resuscitation and/or stabilization of the infant a pediatrician shall be either onsite or called to come in to manage the emergency prior to transport of the infant to a Level II or level III service. All infants requiring mechanical ventilation shall be transferred to a Level III service	Additional language emphasizes and clarifies he requirement
(6) Arrangements for emergency transport to Level II and III centers as stipulated in collaboration agreements. Infants shall be transferred to an appropriate center within geographic proximity except under unusual circumstances such as lack of available bed or by parental request.	(6) Arrangements for emergency transport to Level II and III centers as stipulated in collaboration/**transfer** agreements. Infants shall be transferred to an appropriate center within geographic proximity except under unusual circumstances such as lack of available bed or by parental request.	Addition of transfer component corresponds to additions made to collaboration/transfer agreement requirements in 130.616 (B)
(7) Availability of continuous internal and external electronic fetal monitoring.		
(8) Amniocentesis and ultrasound capabilities.		
(9) Capability of beginning a cesarean surgical birth within 30 minutes of the decision to perform the procedure.	(9) Capability of **readily** beginning a**n emergency** cesarean surgical birth ~~within 30 minutes of~~ when the decision to perform the procedure has been made.	Language change to be consistent with American College of Obstetricians and Gynecologists (ACOG) standard.
(10) Blood for transfusions including O negative and fresh frozen plasma, on a 24 hours a day basis.		
(11) Anesthesiologists shall be available in-house or on-call such that emergency cesarean deliveries can be started within 30 minutes of the recognition of the need for the procedure.	(11**A**) Anesthesiologists shall be **readily** available in-house or on-call such that emergency cesarean deliveries can be started ~~within 30 minutes of~~ **upon** the recognition of the need for the procedure **24 hours a day.**	Language change to be consistent with American College of Obstetricians and Gynecologists (ACOG) standard.
	(11B) Respiratory therapists shall be available on call 24 hours a day.	Ensures availability of services when needed
(12) Radiology services, including ultrasound, on-call on a 24 hours a day basis.	(12) Radiology services, including ultrasound **and portable x-ray**, on-call on a 24 hours a day basis.	Updated to reflect current standards for equipment availability to carry out required functions
(13) Clinical laboratory services, including microchemistry, on-call on a 24 hours a day basis.		

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(14) Care of the retrotransferred stable-growing or recovery infant who does not require the complex medical management needs provided by a Level II or III service.		
(15) The following services on a 24 hours a day basis for infants born in-house and for retrotransfers:	(15) The following **care and** services on a 24 hours a day basis for infants born in-house and for retrotransfers:	
	(a) Emergency management including newborn cardiopulmonary resuscitation and emergent diagnostic placement of umbilical arterial and venous arterial catheter lines. **(b) Neonatal stabilization prior to transfer, including:** **(i) oxygen administration** **(ii) cardio-respiratory monitoring** **(iii) emergency packed red blood cells and fresh frozen plasma** **(iv) glucose management** **(v) intravenous fluid administration** **(vi) antibiotic administration** **(vii) sepsis evaluation, including lumbar puncture and blood cultures** **(viii) thermoregulation** **(ix) provision for parental contact prior to transfer**	This section is reorganized and required services to support good patient care are defined.
(a) Oxygen therapy and the capability to monitor oxygen therapy.	~~(a) Oxygen therapy and the capability to monitor oxygen therapy.~~	
(b) Naso-gastric and oro-gastric feedings.	~~(b) Naso-gastric and oro-gastric feedings.~~	
(c) Sepsis evaluations including lumbar punctures and cultures.	~~(c) Sepsis evaluations including lumbar punctures and cultures.~~	
(d) Peripheral intravenous therapy for hydration and medication administration.	~~(d) Peripheral intravenous therapy for hydration and medication administration.~~	
	(c) Care of the newborn:	
(e) Intramuscular injections.	**(i)** intramuscular injections.	
(f) Phototherapy.	**(ii)** phototherapy.	
(g) Capability to assess and maintain an infant's neutral-thermal environment.	~~(g) Capability to assess and maintain an infant's neutral-thermal environment~~. **(iii) thermoregulation**	
(h) Electronic cardio-respiratory monitoring.	~~(h) Electronic cardio-respiratory monitoring.~~	

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	(iv) fluid management **(v) infant feeding** **(vi) pain assessment and management**	
	(16) Registered pharmacist services with access to neonatal, pediatric and maternal pharmacological resources, at a minimum available by telephone consultation. **(17) Provision for 24-hour access to emergency drugs.**	
(D) Policies and Procedures. The Level I Maternal-Newborn Service shall develop those policies and procedures listed in the General Requirements and the following:		
(1) Policies and procedures for consultation with and/or transfer of mother and/or newborn to level II and III facilities:		
(a) The policies and procedures for maternal transfer shall encourage the delivery at a Level II or III facility of those mothers who are medically assessed as requiring such level of care or whose newborns are anticipated to require the services offered at such level.		
(b) The policies and procedures for maternal transfer shall address the management of premature labor, isoimmunizations, medical complications of pregnancy, as well as antenatal and intrapartal complications of delivery.		
(2) Policies and procedures for management of medical and surgical complications of pregnancy which include, at a minimum, maternal diabetes, organic heart disorder and surgical abdomen.		
(3) Other policies and procedures as deemed appropriate by the hospital perinatal committee.		
Such policies shall be submitted to the Department upon request.		
(E) A Level IB service shall meet the Level I requirements set forth in 105 CMR 130.360(A) through (D) and the following additional requirements**:**	**(E) Level IB Service Designation: The services capabilities include the management of uncomplicated pregnancies and the management of pregnancy complications not requiring the facilities and resources of Level II A, II B or Level III services.** **Provides for the care and management of well newborns, stable infants**	This section added to better distinguish Level IB services from a Level I service. To ensure the validity of a service designation at a IB level, the proposal requires that a hospital

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	born at ≥ 35 weeks gestation, including stable retro-transferred infants not needing level II A, II B or level III services. **A Level I service may be designated as a Level IB service with a continuing care nursery service, if the following additional requirements (E) (1)-(5) are met 24 hours a day, 7 days a week:** All infants requiring mechanical ventilation shall be transferred to a Level III service	seeking the designation be committed to having Level IB services available to newborns 24 hours a day, 7 days a week.
(1) Administration and Staffing.	(1) Administration and Staffing.	
(a) A physician certified by the American Board of Pediatrics with experience in the care of special care infants shall be designated as the medical director of the Continuing Care Nursery.	(a) A physician certified by the American Board of Pediatrics with experience in the care of ~~special care infants~~ **newborns** shall be designated as the medical director of the **Level IB** Continuing Care Nursery **Service. The medical director or his/her designee shall be available on-call 24 hours a day.**	Language adds requirement for management coverage 24 hours a day.
(b) A physician who is either certified or eligible for certification by the American Board of Pediatrics with Continuing Care Nursery privileges shall be available on-call on a 24 hours a day basis.		
(c) The hospital shall designate a registered nurse who has responsibility and accountability for the 24 hour nursing management of the Continuing Care Nursery service. At a minimum, such nurse shall be baccalaureate prepared and have additional education in the specialty area. She or he shall have at least two years experience in the specialty area and meet the qualifications for the management position as defined by hospital policy.	(c) **(i)** The hospital shall designate a registered nurse who has responsibility and accountability for the 24 hour nursing management of the Continuing Care Nursery service. At a minimum, such nurse shall be baccalaureate prepared **(master's preferred)** and have additional education in the specialty area. She or he shall have at least two years experience in the specialty area and meet the qualifications for the management position as defined by hospital policy. **(c) (ii) The hospital shall provide a baccalaureate prepared nurse educator with dedicated responsibility for coordinating and providing education activities to enhance staff knowledge of relevant procedures and technological advances for staff of the maternal and newborn service**.	Addition of nurse educator to coordinate and provide education activities better ensures that staff remain competent and skilled.
(d) A respiratory therapist with pediatric experience shall be present in-house to provide	(d) A respiratory therapist ~~with pediatric experience~~ **trained in neonatal**	Addition better ensures that appropriately trained

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consultation on oxygen therapy and equipment maintenance.	**transition and disease pathology (e.g. NRP)** shall be present in-house 24 hours a day to provide consultation on oxygen therapy and equipment maintenance.	staff provides care.
(e) A medical engineer shall be responsible for the maintenance and safe functioning of specialized equipment per written hospital policy.		
(2) Services. The level IB Continuing Care Nursery shall provide the following:	(2) Services. **For designation as a** ~~The~~ Level I B Continuing Care Nursery **Service, the hospital** shall provide **Level I care and services in addition to** the following **Level I B care and services 24 hours a day, 7 days a week:**	Revision updates list of services to distinguish a level 1B from Level 1A. To ensure the Level 1B is able to provide the required services of a Level 1B consistency, specific language is proposed to ensure 24 hour, 7day a week capabilities. In the past, certain level 1B units could only provide enhanced care intermittently and not consistently. We proposed eliminating the designation of 'part-time' level 1B services.
(a) Continuous oxygen administration via nasal cannula and hood.	(a) Continuous oxygen administration~~ via nasal cannula and hood~~. **and short term oxygen therapy via nasal cannual and/or oxyhood.**	Updated to reflect current standards for service availability necessary to carry out required care.
(b) Umbilical artery/vein line insertion and maintenance.	(b) ~~Umbilical artery/vein line insertion and maintenance~~. **Emergent diagnostic placement of umbilical arterial catheter, umbilical venous catheter and peripheral inserted central catheter (PICC)**	Updated to reflect current standards for service availability necessary to carry out required care.
	(c) Long term antibiotic therapy via PICC **(d) Gavage feedings** **(e) Management of mild apnea of prematurity.**	These specific services added to ensure availability for retrotransferred infants requiring them.
(c) Continuous involvement of parents in infant's care and opportunity for parents to room-in for predischarge education in caring for the infant.	~~(c)~~ **(f)** Continuous involvement of parents in infant's care and opportunity for parents to room-in for pre-discharge education in caring for the infant.	Renumbered
(d) Where indicated, a plan for positive infant stimulation including but not limited to tactile, kinesthetic, auditory and visual measures such as rocking, touching, and vocalization to support positive and reciprocal interaction between infant and parents.	~~(d)~~ **(g)** Where indicated, a plan for positive infant stimulation including but not limited to tactile, kinesthetic, auditory and visual measures such as rocking, touching, and vocalization to support positive and reciprocal interaction between infant and parents.	Renumbered
(e) Written discharge planning.	~~(e)~~ **(h)** Written discharge planning	Renumbered

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(f) Radiology, including portable x-ray on a 24 hours a day basis.	**(i)** Radiology, including portable x-ray on a 24 hours a day basis. **Access to radiologist on staff, available daily to interpret neonatal studies, such as chest and abdominal radiographs and cranial ultrasounds**	Clarification to ensure intent of requirement
(g) In-house clinical laboratory services including microchemistry on a 24 hours a day basis.	~~(g)~~ **(j)** In-house clinical laboratory services including microchemistry on a 24 hours a day basis	
(h) Respiratory therapy services, in-house on a 24 hours a day basis.	~~(h)~~ **(k)** Respiratory therapy services, in-house on a 24 hours a day basis.	
	(l) Access to ophthalmologist with experience diagnosing conditions such as retinopathy of prematurity.	Necessary to ensure continuity of care for very low birth weight infants who are retrotransferred.
	(m) Access to the services of a developmental specialist	Necessary to ensure continuity of care for very low birth weight infants who are retrotransferred.
(4) Policies and Procedures for Transfer. The Level I-B Continuing Care Nursery shall have written policies and procedures for the following:		
(a) consultation with and/or transfer to a Level II or III unit. All infants requiring mechanical ventilation shall be transferred to a Level III unit,		
(b) the circumstances when the presence of a pediatrician is required. A pediatrician shall be present during the delivery of an infant anticipated to require stabilization and during the period awaiting actual transfer of the infant to a Level II or III facility.	(b) the circumstances when the presence of a ~~pediatrician~~ **qualified provider designated to be responsible for newborn resuscitation and stabilization** is required. A ~~pediatrician~~ **qualified provider with sole responsibility for resuscitation** shall be present during the delivery of an infant anticipated to require stabilization and during the period awaiting actual transfer of the infant to a Level II or III facility.	Revision specifies responsibility rather than provider type.
(5) Other Policies and Procedures. The Level I-B Continuing Care Nursery shall have written policies and procedures for the following:		
(a) Nursing orientation and ongoing education including theory and skills required to function in the Level I-B Continuing Care Nursery.		
(b) If therapeutic formulas are made on-site, preparation and sealing of containers to prevent tampering.		
	(c) Policy and procedures for the care and management of infants with mild apnea of prematurity, neonatal abstinence assessment and	Updates requirements for policies and procedures to support Level IB care.

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	management, care and management of PICC line and oxygen therapy, feeding protocols, criteria for neonatology consult and transfer to Level III service.	
(c) Other policies and procedures as deemed appropriate by the hospital perinatal committee.	~~(c)~~ **(d)** Other policies and procedures as deemed appropriate by the hospital perinatal committee	Renumbered
130.640: Level II: Community-Based Maternal-Newborn Service with a Special Care Nursery	130.640: Level II **A and II B**: Community-Based Maternal-Newborn Service with a Special Care Nursery A service shall be eligible for designation as a Level II service with a special care nursery if one of the following conditions is met: a) the service has a minimum of 1,500 births per year in any one of the past three years **prior to the initiation of the service** b) the service has satisfactorily demonstrated to the Department that a minimum volume of 1500 births per year will be reached in the next three years; or c) the service has satisfactorily demonstrated to the Department that the hospital's role in assuring access to maternal and newborn care warrants such designation. **A Level II service shall maintain a minimum volume of 1,500 births following the designation.** **Level II A capabilities include the management of uncomplicated pregnancies and the management of pregnancy complications not requiring the facilities and resources of level II B or level III services. Level IIA capabilities include the care and management of the stable to moderately ill neonate: well newborns, premature infants ≥ 34 weeks gestation, and infants who require special care services (including retro-transferred infants)**	Propose to divide current Level II services into 2 distinct categories, II A and Level II B. The change recognizes the newly defined levels in the accordance with the American Academy of Pediatrics': *Guidelines for Newborn Care.* In general, the literature supports a minimum census or volume requirement for a hospital to maintain adequate experience The proposed change further defines certain Level II services (Level II B services) that will provide enhanced services, including the capabilities to care for neonates of lower gestational age than those neonates cared for in Level II A services. In particular, the proposed Level II B service will have the capabilities of caring for neonates with respiratory distress requiring CPAP (Continuous Positive Airway Pressure) and STMV (Short Term Mechanical Ventilation). The proposed

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	Level II B capabilities include the care and management of uncomplicated pregnancies and the management of pregnancy complications not requiring the facilities and resources of a level III service. **Level II B capabilities include the care and management of the stable to moderately ill neonate, well newborns, premature infants delivering at ≥ 32 weeks gestation, and infants who require special care services (including retro-transferred infants). Level II B services will include the care of infants requiring Continuous Positive Airway Pressure (CPAP) and may include the care of infants requiring Short Term Mechanical Ventilation (STMV) up to 24 hours in accordance with DPH standards**	regulations include additional staffing and resource requirements for designation as a Level II B service. The proposal to include two categories of level 2 services (level II A and level IIB) is intended 1) To reflect the actual distinctions that exist among currently designated level 2 units in Massachusetts and 2) To establish requirements for level 2 units that have adequate staff, resources and facilities to care for moderately sick neonates with more complex needs, including the option for Level II B services to care for newborns needing short term mechanical ventilation (up to 24 hours). The 24-hour limit is consistent with American Academy of Pediatrics guidelines
The Level II Community-Based Maternal-Newborn Service shall meet the requirements contained in 105 CMR 130.600 through 130.628 and, in addition, the following:	The Level II **A and II B** Community-Based Maternal-Newborn Service**s** shall meet the requirements contained in 105 CMR 130.600 through 130.628 and, in addition, the following:	
(A) Maternal Service.	(A) Maternal Service.	
(1) Collaboration Agreements. The Level II service shall establish formal written collaboration-agreements with at least one Level III hospital.	(1) Collaboration/**Transfer** Agreements. The Level II service shall establish formal written collaboration/**transfer** agreements with at least one Level III hospital **with maternal services.**	Addition of transfer component corresponds to additions made to collaboration/transfer agreement requirements in 130.616 (B)
(2) Administration and Staffing.		
(a) A physician certified by the American Board of Obstetrics and Gynecology shall be designated medical director of the maternal service. This physician shall collaborate with the pediatrician responsible for newborn patients in the medical management of the entire		

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maternal-newborn service.		
(b) A physician certified or eligible for certification by the American Board of Obstetrics and Gynecology with full privileges shall be available on-call on a 24 hours a day basis.		
(c) The hospital shall designate a registered nurse who has responsibility and accountability for the 24 hour nursing management of the maternal service. At a minimum, such nurse shall be prepared at the baccalaureate level and have additional education in the specialty area. She or he shall also have at least two years experience in the specialty area and meet the qualifications for the management position as defined by hospital policy.		
	(c i) In a Level II A service, a registered nurse educator, prepared at the baccalaureate level (masters preferred) shall have dedicated responsibility for coordinating and providing education activities to enhance staff knowledge of relevant procedures and technological advances for staff of the maternal and newborn service. **(c ii) In a Level lI B service, at a minimum a full time mastered prepared clinical nurse specialist with clinical experience in perinatology or neonatology or a neonatal nurse practitioner shall be available with dedicated responsibility for coordinating education for maternal and newborn staff,**	Addition of nurse educator to coordinate and provide education activities better ensures that staff remain competent and skilled.
(d) A licensed social worker with experience in maternal-child health shall be available to provide services to mothers.		
(e) A dietician registered by the American Dietetic Association and with expertise in maternal care shall be available for consultation to both normal and high-risk mothers.		
(3) Services. The Level II Maternal Service shall provide the following:		
(a) Social work services.		
(b) Nutritional consultation.	(b) Nutritional consultation by a registered dietician experienced in maternal-newborn nutritional needs **available 7 days a week.**	Ensures availability of services when needed
(c) Medical risk assessment, resuscitation and stabilization of the mother prior to transport to a Level III facility if required.		
(d) Availability of continuous internal and external electronic-fetal monitoring.		

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(e) Capability of beginning a cesarean surgical birth within 30 minutes of the decision to perform the procedure.	(e) Capability of **readily** beginning a**n emergency** cesarean surgical birth ~~within 30 minutes of~~ **when** the decision to perform the procedure **has been made.**	Language change to be consistent with American College of Obstetricians and Gynecologists (ACOG) standard.
(f) Blood for transfusions, including O negative and fresh frozen plasma, on a 24 hours a day basis		
(g) Anesthesia, in-house or on call, on a 24 hours a day basis, such that emergency cesarean deliveries can be started within 30 minutes of recognition of the need for the procedure.	(g) Anesthesia, in-house or on call, on a 24 hours a day basis, such that emergency cesarean deliveries can be **readily** started **upon** ~~within 30 minutes of~~ recognition of the need for the procedure.	Language change to be consistent with American College of Obstetricians and Gynecologists (ACOG) standard.
(h) Radiology, in-house, on a 24 hours a day basis		
(i) Clinical laboratory services including on-unit capabilities for microchemical fetal blood sample monitoring on a 24 hours a day basis.	(i) Clinical laboratory services including ~~on unit~~ **in-house** capabilities for microchemical fetal blood sample monitoring on a 24 hours a day basis.	No longer requires services on patient unit
(j) Capability to perform ultrasound and amniocentesis 24 hours a day.	(j) Capability to perform ultrasound and amniocentesis **in-house** 24 hours a day.	
(k) Subspecialty services for the mothers including, but not limited to, general surgery, cardiology, urology, internal medicine, hematology and neurology.		
(l) Access to genetics counseling.		
(4) Policies and Procedures. The Level II Maternal Service shall have written policies and procedures as required by 105 CMR 130.600 through 130.628 and, in addition, the following:		
(a) An organized plan for a team approach to deliveries that require the presence of a pediatrician and an anesthesiologist in the delivery room and properly defines their responsibilities. The hospital's perinatal committee shall establish policies, definitions, and conditions of delivery requiring a team approach.		
(b) Policies and procedures for consultation with specialists for medical management and/or transfer of the mother to a Level III facility.		
(i) Policies and procedures for maternal transfer shall address the management of premature labor, medical complications of pregnancy, as well as antenatal complications of delivery.		
(ii) Policies and procedures for management of medical and surgical complications of pregnancy shall include but not be limited to maternal diabetes, iso-immunization, organic heart disease and surgical abdomen.		

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	(iii) The policies for maternal transfer shall encourage the delivery at a Level III facility of those mothers who are medically assessed as requiring such level of care or whose newborn(s) are anticipated to require the services of such level.	The language is consistent with the recommendations of the American Academy of Pediatrics and the American College of Obstetrics and Gynecology outlined in the current *Guidelines for Perinatal Care* to support improved perinatal outcomes.
(c) Other policies and procedures as deemed appropriate by the hospital perinatal committee.		
Such policies shall be submitted to the Department upon request.		
(B) **Special Care Nursery.**		
(1) Collaboration Agreements. Each hospital providing a Level II maternal-newborn service shall establish formal written collaboration agreements with at least one Level III hospital.	(1) Collaboration/**Transfer** Agreements. Each hospital providing a Level II maternal-newborn service shall establish formal written collaboration/**transfer** agreements with at least one Level III hospital.	Addition of transfer component corresponds to additions made to collaboration/transfer agreement requirements in 130.616 (B)
(2) Administration and Staffing.		
(a) A physician certified by the American Board of Pediatrics who has qualified to appear for the neonatology board shall be designated the medical director of the Special Care Nursery. A pediatrician meeting the requirements of 105 CMR 130.640(B)(2)(b) shall be designated to act in the absence of the director.		
(b) A physician certified or eligible for certification by the American Board of Pediatrics with Special Care Nursery privileges shall be available on-call on a 24 hours a day basis.	**(b) A neonatologist shall be available on-call on a 24 hours a day basis.**	
(c) The hospital shall designate a registered nurse who has responsibility and accountability for the 24 hour nursing management of the Special Care Nursery service. At a minimum, such nurse shall be baccalaureate-prepared and have additional education in the neonatology specialty area. She or he shall have at least two years experience in the specialty area and meet the qualifications for the management position as defined by hospital policy.		
(d) A masters-prepared social worker with a background in maternal- child health shall be available as needed.		
(e) A dietician registered by the American Dietetic Association and with pediatric experience		

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shall be available as needed.		
(f) A respiratory therapist with pediatric experience shall be present in-house on a 24 hours a day basis to provide consultation on oxygen therapy and equipment maintenance.		
(g) A medical engineer shall be responsible for the maintenance and safe functioning of specialized equipment per written hospital policy.		
(3) Special On-site Staffing Requirements. Each hospital providing special care nursery services shall provide on-site coverage 24 hours a day by either a pediatrician who meets the requirements of 105 CMR 130.640(B)(3)(a) or neonatal nurse practitioner who meets the requirements of 105 CMR 130.640(B)(3)(b), who shall be immediately available to the special care nursery and the delivery room.	(3) Special On-site Staffing Requirements. Each hospital providing special care nursery services shall provide on-site coverage 24 hours a day by either a **neonatologist or a** pediatrician who meets the requirements of 105 CMR 130.640(B)(3)(a) or neonatal nurse practitioner who meets the requirements of 105 CMR 130.640(B)(3)(b), who shall be immediately available to the special care nursery and the delivery room.	
(a) Pediatricians. A pediatrician qualified to provide on-site coverage in the special care nursery shall be either a pediatric resident who, at a minimum, has completed the first year of post-graduate residency training or a pediatrician who is certified or eligible for certification by the American Board of Pediatrics. Pediatricians shall meet the hospital's requirements for special care nursery privileges. Pediatric residents shall meet criteria for special care nursery coverage established by the Director of the special care nursery. At a minimum, criteria for privileges and coverage shall include the specific clinical skills to provide emergency newborn resuscitation in the delivery room and essential special care nursery skills such as intubation, emergency pneumothorax management, umbilical artery catheterization, and drawing arterial blood gases. Before assignment to provide on-site coverage, pediatricians and residents shall successfully complete the American Heart Association/ American Academy of Pediatrics neonatal resuscitation course (or an equivalent).	(a) Pediatricians. A pediatrician qualified to provide on-site coverage in the special care nursery shall be either a pediatric resident who, at a minimum, has completed the ~~first~~ **second** year of post-graduate residency training **with at least 2 months neonatal intensive care unit rotations** or a pediatrician who is certified or eligible for certification by the American Board of Pediatrics. Pediatricians shall meet the hospital's requirements for special care nursery privileges. Pediatric residents shall meet criteria for special care nursery coverage established by the Director of the special care nursery. At a minimum, criteria for privileges and coverage shall include the specific clinical skills to provide emergency newborn resuscitation in the delivery room and essential special care nursery skills such as intubation, emergency pneumothorax management, umbilical artery catheterization, and drawing arterial blood gases. Before assignment to provide on-site coverage, pediatricians and residents shall successfully complete the American Heart Association/ American Academy of Pediatrics neonatal resuscitation course (or an equivalent).	Revision better ensures that resident has appropriate experience to care infants in the special care nursery
(b) Neonatal Nurse Practitioner.		
(i) A neonatal nurse practitioner qualified to provide on-site coverage in the special care nursery		

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shall		
a. preferably have a master's degree but at a minimum have a baccalaureate degree,		
b. be certified as a neonatal nurse practitioner by a nationally recognized organization, and		
c. be licensed to practice in the expanded role by the Massachusetts Board of Registration in Nursing.	c. be ~~licensed~~ **authorized** to practice ~~in the expanded role~~ **as an advanced practice registered nurse** by the Massachusetts Board of Registration in Nursing.	Language updated.
(ii) Before assignment to provide on-site coverage, each neonatal nurse practitioner shall successfully complete the American Heart Association/ American Academy of Pediatrics neonatal resuscitation course (or an equivalent).		
(iii) There shall be a planned schedule for the practitioner to rotate regularly to the level III service with which the level II service has a collaboration agreement. Rotation to the level III service shall occur with such frequency as to assure that the neonatal nurse practitioner has the opportunity to maintain skills in the emergency procedures outlined in 105 CMR 130.640(B)(3)(a). At a minimum, the rotation shall occur annually. The practitioner shall be periodically evaluated by both the level II and level III services.		
(iv) Neonatal nurse practitioners shall be credentialed through the hospital's nursing department and medical staff and function under approved written guidelines for practice. Neonatal nurse practitioners shall also meet the criteria for delivery room and special care nursery coverage established by the director of the special care nursery. Criteria shall include the skills necessary to provide emergency care to newborns as outlined in 105 CMR 130.640(B)(3)(a).		
(v) The nurse practitioner providing level II coverage shall have at least one year's recent experience functioning as a neonatal nurse practitioner on a service that provides high risk obstetrical and neonatal intensive care unit services.		
(vi) Neonatal nurse practitioners shall be part of a team providing patient care and not retained only to provide off hour or holiday coverage at the level II service. The schedule for coverage of the delivery room and special care nursery shall reflect that pediatricians and neonatal nurse practitioners who are members of the team share responsibility for covering all shifts and collaborate in the ongoing care of infants and their families and in professional education activities.		

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(vii) There shall be written policies and procedures outlining the specific criteria for summoning pediatrician or neonatologist back-up coverage for consultation and for on-site assistance in the delivery room and special care nursery.		
(4) Services. The Level II Special Care Nursery shall provide the following:	(4) Services. The Level II **A and II B** Special Care Nursery shall provide the following:	
(a) Social work services.		
(b) Nutritional consultation.		
(c) Risk-assessment, stabilization and triage to a level III services.		
(d) Provision of a neutral-thermal environment.		
(e) Continuous oxygen administration via nasal cannula and hood.	(e) Continuous **and long-term** oxygen administration via nasal cannula and hood, **including oxygen saturation monitoring,**	Updated to reflect current standards for service availability necessary to carry out required care
	(f) Pharmacological treatment of apnea of prematurity	Updated to reflect current standards for service availability necessary to carry out required care
(f) Capabilities to insert and maintain intravenous therapy for hydration and medication administration on a 24 hours a day basis.	~~(f)~~ **(g)** Capabilities to insert and maintain intravenous therapy for hydration and medication administration on a 24 hours a day basis	Renumbered
(g) Umbilical artery/vein line insertion and maintenance.	~~(g)~~ **(h)** Umbilical artery **and venous catheter** ~~/vein line~~ insertion and maintenance.	Updated to reflect current standards for service availability necessary to carry out required care
(h) Continuous electronic cardio-respiratory monitoring.	~~(h)~~ **(i)** Continuous electronic cardio-respiratory monitoring.	
(i) Blood transfusion capability (exchange transfusion optional).	~~(i)~~ **(j)** Blood transfusion capability (exchange transfusion optional).	
(j) Naso-gastric, oro-gastric and oro-jejunal feedings.	~~(j)~~ **(k)** Naso-gastric, oro-gastric and oro-jejunal feedings.	
(k) Sepsis evaluations including lumbar punctures and cultures.	~~(k)~~ **(l)** Sepsis evaluations including lumbar punctures and cultures.	
(l) Peripheral alimentation.	~~(l)~~ **(m)** ~~Peripheral alimentation~~. Parental nutrition	Updated to reflect current standards for service availability necessary to carry out required care
(m) Phototherapy.	~~(m)~~ **(n)** Phototherapy.	
(n) Continuous involvement of parents in infant's care and opportunity for parents to room-in for predischarge education in caring for the infant.	~~(n)~~**(o)** Continuous involvement of parents in infant's care and opportunity for parents to room-in for pre-discharge education in caring for the infant.	
(o) Where indicated, a plan for positive infant stimulation including but not limited to tactile, kinesthetic, auditory and visual measures such as rocking, touching, and vocalization to support positive and reciprocal interaction between infant and parents. (Attention shall also be given to	~~(o)~~**(p)** Where indicated, a plan for positive infant stimulation including but not limited to tactile, kinesthetic, auditory and visual measures such as rocking, touching, and vocalization to support positive and reciprocal	

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elimination of negative or extraneous environmental stimuli.)	interaction between infant and parents. (Attention shall also be given to elimination of negative or extraneous environmental stimuli.)	
(p) Written discharge planning.	(~~p~~)**(q)** Written discharge planning.	
(q) Arrangements for transport between Level I and Level II facilities as stipulated in collaborative agreements.	(~~q~~) **(r)** Arrangements for transport between Level I and Level II facilities as stipulated in ~~collaborative~~ **transfer** agreements.	Collaborative agreements re-drafted as transfer agreements to reflect more accurately the elements of patient transfer.
(r) Care of the retrotransferred infant from Level III after the acute phase of illness has passed, including infants who require for ongoing medical supervision and management. Placement at a Level II facility shall be jointly agreed upon at least by the medical staff responsible for the infant's care at the Level II and Level III facilities.	(~~r~~) **(s)** Care of the retrotransferred infant from Level III after the acute phase of illness has passed, including infants who require for ongoing medical supervision and management. Placement at a Level II facility shall be jointly agreed upon at least by the medical staff responsible for the infant's care at the Level II and Level III facilities.	
(s) Radiology, including portable x-ray capabilities, in-house, on a 24 hours a day basis.	(~~s~~) **(t)** Radiology, including portable x-ray capabilities, in-house, on a 24 hours a day basis.	
(t) In-house clinical laboratory services including microchemistry on a 24 hours a day basis.	(~~t~~) **(u)** In-house clinical laboratory services including microchemistry on a 24 hours a day basis.	
(u) Respiratory therapy services, in-house, on a 24 hours a day basis.	(~~u~~) **(v)** Respiratory therapy services, in-house, on a 24 hours a day basis.	
(v) Access within the facility or through arrangement with Level III facilities to subspecialty services or consultation with pediatric surgery, neurology, cardiology and genetics.	(~~v~~)**(w)** Access within the facility or through arrangement with Level III facilities to subspecialty services or consultation with pediatric surgery, neurology, cardiology and genetics.	
(5) Policies and Procedures For Transfer.		
(a) The Special Care Nursery shall have written policies and/or procedures for consultation with and/or transfer to a Level III unit. All infants requiring mechanical ventilation shall be transferred to a Level III Unit.	(a) ~~The~~ **A Level II A and Level II B** Special Care Nursery shall have written policies and/or procedures for consultation with and/or transfer to a Level III unit. All infants **in a designated Level IIA service** requiring mechanical ventilation shall be transferred to a Level III Unit**. All infants in a designated Level II B service requiring mechanical ventilation for more than 24 hours shall be transferred to a Level III service.**	Propose establishing a Level II B service that has the capability of providing short term mechanical ventilation (no more than 24 hours). The time limit of 24 hours is consistent with American Academy of Pediatrics recommendations for a community hospital service. .

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Such policies shall be submitted to the Department upon request.		
(b) A mechanical ventilator or CPAP (Continuous Positive Airway Pressure) may be initiated and used in a Special Care Nursery prior to such transfer only when the Medical Director of the Special Care Nursery approves such use and only when all of the following conditions are met:		
(i) A neonatologist remains at the infant's bedside at all times.		
(ii) A respiratory therapist with experience in neonatal ventilation remains at the infant's bedside at all times.		
(iii) The Special Care Nursery is arranging for transport of the infant to the bevel III unit.		
(iv) The mechanical ventilator is used only while the infant is awaiting the transport.		
(6) Other Policies and Procedures. The Special Care Nursery shall have written policies and procedures for the following:		
(a) Nursing orientation and ongoing education including theory and skills required to function in the Special Care Nursery.		
(b) If therapeutic formulas are made on-site, policies governing preparation and sealing containers to prevent tampering.		
(c) Other policies and procedures as deemed appropriate by the hospital perinatal committee.		
	(C) Level II B Special Care Nursery: A hospital with a Level II service may apply for designation as a Level II B Special Care Nursery Service, if a) the hospital had 2000 or more deliveries for each of the 3 years after designation as a Level II service; or b) the hospital had 2500 or more deliveries for each of the 2 years after designation as a Level II service. (1) **In compliance with Department guidelines for CPAP and STMV a) the Level II B Special Care Nursery Service shall provide care to certain neonates requiring ongoing Continuous Positive Airway Pressure (CPAP) therapy and b) after the Special Care Nursery service has experience providing CPAP therapy for a minimum of one year, the hospital may seek Department approval to also**	The Level II B services requirements described in this section of the proposed changes recognize advanced technology and the increased use of antenatal steroids and surfactant. Proposed regulations require Level II B services to meet Department guidelines that include elements necessary to provide safe care to neonates, including low birth weight neonates diagnosed and treated for respiratory distress at a hospital designated as a Level II B service. The Department will prepare guidelines in

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	provide short term mechanical ventilation (STMV) for neonates determined to need ventilatory support for no more than 24 hours to resolve uncomplicated respiratory distress. A neonatologist shall be in-house and available to the service when neonates are receiving STMV. **(2) Neonates requiring high-frequency ventilation support or services beyond the capabilities of the Level II B service and staff shall be transferred to an appropriate Level III hospital as soon as the responsible neonatologist determines, in consultation with the Level III service, that it is safe to do so.** **(3) As soon as the Level II B service anticipates or determines that a neonate requires mechanical ventilation to resolve uncomplicated respiratory distress, the neonatologist responsible for the neonate's care shall immediately consult with the collaborating Level III service and agree on a plan of care for the neonate as long as the neonates condition is stable and improving and there are indicators that the respiratory problem is resolving. The responsible medical staff shall document, in the neonate's medical record, the consultation and agreed upon plan of care.** (4) **As soon as it is anticipated or determined that the neonate will require mechanical ventilation for more than 24 hours, the neonate shall be transferred to an appropriate Level III hospital as soon as the responsible neonatologist determines, in consultation with the Level III service, that it is appropriate to do so.** (5) **Level IIB services shall meet the staffing, policy, collaboration, quality assurance and data collection requirements outlined in Department guidelines**.	consultation with the Perinatal Advisory Committee and will address staffing, staffing competencies, institutional capacity, consultation requirements, collaboration and transfer agreements and quality assurance.
(7) Records. In addition to meeting the requirements for records contained in 105 CMR 130.627(B), the record of a newborn treated in a Special Care Nursery shall also contain		

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documentation of the following:		
(a) Diagnostic and treatment modalities.		
(b) Family-infant interactions.		
(c) Parents' understanding of infant's condition, progress and treatment.		
(d) Parent education and involvement in both normal and specialized care-giving.		
(e) Where indicated, the plan for and patient response to infant stimulation program.		
(f) Referrals to community agencies such as parent support groups, visiting nurse associations and early intervention programs.		
(8) Environment and Equipment. The Special Care Nursery shall contain the following:		
(a) Incubators.		
(b) Cardio-respiratory monitors with high/low alarm.		
(c) Warming table(s).		
(d) Infusion pumps.		
(e) Oxygen humidification and warming system. (The respiratory therapist shall check machine functioning and provide scheduled maintenance per written hospital policy.)		
(f) Oxygen analyzer.		
(g) Umbilical artery/vein catheterization equipment.		
(h) Emergency medications and equipment.		
(i) A separate formula preparation area if therapeutic formulas are made on-site. The preparation area shall have a work counter, sink for handwashing and storage facility.		
	(j) Availability of hospital grade breast pump and collection kits in numbers sufficient to meet needs and separate refrigerator/freezer for expressed breast milk.	Updated to reflect current standards for equipment availability needed to support breastfeeding
(9) Construction and Arrangement of Special Care Nursery. The construction and arrangement of the Special Care Nursery shall permit immediate observation and accessibility of infants to personnel. Total nursery space, exclusive of anteroom, shall provide an average floor space of 50 square feet for each incubator or bassinet.		
130.650: Level III - Perinatal Center Neonatal Intensive Care Unit	130.650: ~~Level III - Perinatal Center Neonatal Intensive Care Unit~~ **Level**	The term 'Perinatal Center' is eliminated and

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	III Maternal and Newborn Service or a Freestanding Pediatric Hospital with Neonatal Subspecialty Services.	replaced by 'Level III Maternal and Newborn Service or a Freestanding Pediatric Hospital with Neonatal Subspecialty Services. The proposed revision establishes the requirement that a neonatal intensive care unit must be located in a hospital that also provides and meets the requirements of a level III maternal service or in a Freestanding Pediatric Hospital. The language of the current regulations permits any hospital to be eligible to apply for NICU beds without specifically requiring the hospital to meet corresponding requirements for level III maternal service.
The Level III service shall meet the requirements contained in 105 CMR 130.600 through 130.628 and, in addition, the following requirements:	**The maternal service has the capabilities to manage complex maternal conditions with the expertise of a Critical Care Obstetrics Team.** **The Level III maternal and newborn service has the capabilities to provide care for stable to severely ill neonates: well newborns, premature infants, and infants who require neonatal intensive care services. The service provides newborn care to patients with routine medical needs, as well as to those with actual medical problems.** **A service shall be eligible for designation as a Level III service with a neonatal intensive care nursery if one of the following conditions is met:** **(a) the service has a minimum of 2,000 births per year in any one of the past three years ;or** **(b) the service has satisfactorily demonstrated to the Department that a minimum volume of 2,000 births per year will be reached in the next three years; or** **(c) the service has satisfactorily demonstrated that the percent of low birth weight infants (<2,500 grams) delivered is no less than ten percent of the annual births.**	The addition of measure of use standards better ensures a level III service has the capacity to maintain the competencies and skills needed to care for the sickest neonates. In general, the literature supports a minimum census or volume requirement for a hospital to maintain adequate experience

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	The Level III service shall meet the requirements contained in 105 CMR 130.600 through 130.628 and, in addition, the following requirements:	
(A) Maternal Service.		
(1) Administration and Staffing.		
(a) A physician certified by the American Board of Obstetrics and Gynecology with training and experience in perinatal medicine shall be designated medical director of the maternal service. This obstetrician shall collaborate with the neonatologist responsible for the neonatal intensive care unit in the medical management of the maternal-newborn service.	a) A physician certified by the American Board of Obstetrics and Gynecology with ~~training and experience in perinatal medicine~~ **a subspecialty (special competency) in maternal- fetal medicine** shall be designated medical director of the maternal service. This obstetrician shall collaborate with the neonatologist responsible for the neonatal intensive care unit in the medical management of the maternal-newborn service.	Language updated
(b) A physician either certified or eligible for certification by the American Board of Obstetrics and Gynecology shall be on-call on a 24 hours a day basis.	(b) A physician ~~either~~ certified ~~or eligible for certification~~ by the American Board of Obstetrics and Gynecology **with full privileges** shall be ~~on-call~~ **available in-house** on a 24 hours a day basis.	Proposed requirement for certified obstetrician added to support the level of care and severity of risk of mothers cared for in a Level III service. Addition related to hospital privileges recognizes the hospital 's responsibility to determine qualifications necessary for practice.
(c) An obstetrician in training who has completed the second year of post-graduate residency shall be immediately available to the unit, in-house, on a 24 hours a day basis.		
(d) The hospital shall designate a registered nurse, who has responsibility and accountability for the 24 hours a day nursing management of the Level III Maternal Service. At a minimum, such nurse shall be baccalaureate-prepared and have additional education in the specialty area. She or he shall also have at least three years of clinical experience, two of which are in the specialty area, and, in addition, meet the qualifications for the position as defined by hospital policy.	(d) The hospital shall designate a registered nurse, who has responsibility and accountability for the 24 hours a day nursing management of the Level III Maternal Service. At a minimum, such nurse shall be ~~baccalaureate-~~ **masters-**prepared and have additional education in the **maternal** specialty area. She or he shall also have at least ~~three~~ **five** years of clinical experience, two of which are in the specialty area, and, in addition, meet the qualifications for the position as defined by hospital policy. (***the requirement for a masters degree may be waived for individuals holding this position at the time of the promulgation of the regulation.)***	Enhanced standard for nurse manager's education and experience qualifications supports the goal of ensuring a high quality of care.

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	Qualified registered nurses shall be on duty to care for maternal patients on a 24 hour a day basis. The team of nurses shall demonstrate competencies in critical care and be Advanced Cardiac Life Suppport certified. **A full time mastered prepared clinical nurse specialist with clinical experience in neonatology or perinatology or a neonatal nurse practitioner shall be available with dedicated responsibility for coordinating the inservice education for maternal and newborn staff.**	Enhanced standard for nurse coverage supports the goal of ensuring a high quality of care 24 hours a day for service providing care to high risk mothers and newborns.
(e) A masters-prepared social worker with experience in maternal-child health shall be available to provide services to mothers as needed.	(e) ~~A masters-prepared social worker with experience in maternal-child health shall be available to provide services to mothers as needed.~~ **A masters-prepared licensed social worker with experience in assessment of perinatal patients (mother /infant dyad), education, discharge planning, community follow-up programs, referrals and home care arrangements shall be available as needed to meet patient needs.**	Enhanced standard for social work experience supports the goal of ensuring a high quality of care for service providing care to high-risk mothers and newborns.
(f) A dietician registered by the American Dietetics Association with expertise in maternal care shall be available for consultation to mothers as needed.	(f) A dietician registered by the American Dietetics Association with expertise in ~~maternal care shall be available for consultation to mothers as needed.~~ **both normal and high risk maternal-newborn nutritional needs and with access to neonatal nutritional resources available 7 days a week.**	Enhanced standard for availability of nutritional services supports the goal of ensuring a high quality of care for service providing care to high-risk mothers and newborns.
(2) Services. The Level III Maternal Service shall provide the following:		
(a) Social work services.		
(b) Nutritional consultation.		
(c) Medical risk assessment and resuscitation.		
(d) Availability of continuous internal and external electronic-fetal monitoring.		
(e) Capability of beginning a cesarean surgical birth within 15 minutes of the decision to	(e) Capability of **immediately** beginning an emergency cesarean surgical	Language change to be consistent with American

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perform the procedure.	birth ~~within 15 minutes of~~ **after** the decision to perform the procedure.	College of Obstetricians and Gynecologists (ACOG) standard.
(f) Blood for transfusions, including O negative and fresh frozen plasma, on a 24 hours a day basis.		
(g) Anesthesia, in-house, on a 24 hours a day basis.		
(h) Radiology, in-house, on a 24 hours a day basis.	(h) Radiology **and imaging** in-house, on a 24 hours a day basis.	Updated language
(i) Clinical laboratory services including on-unit capabilities for microchemical fetal blood sample monitoring on a 24 hours a day basis.		
(j) 24 hours a day capability for ultrasound and amniocentesis.		
(k) Access within the facility or through referral to another Level III facility to intrauterine transfusions and surgery.		
(l) Adult subspecialty services including general surgery, thoracic surgery, neurosurgery, cardiology, urology, internal medicine, hematology, neurology, genetics and psychiatry.		
	(m) **Intensive care unit services and invasive cardio-vascular monitoring**	Addition of such services required to support high-risk mothers.
(3) Policies and Procedures. In addition to the policies and procedures required pursuant to 105 CMR 130.600 through 130.628 the level III Maternal Services shall develop policies and procedures for the following:		
(a) Admission and transfer criteria.		
(b) Maternal/fetal research.		
(c) Other policies and procedures as deemed appropriate by the hospital perinatal committee.		
Such policies and procedures shall be submitted to the Department upon request.		
(B) Neonatal Intensive Care Unit.		
(1) Administration and Staffing.		
(a) A board-certified neonatologist shall be designated the medical director of the Neonatal Intensive Care Unit.	(a) A board-certified neonatologist shall be designated the medical director of the Neonatal Intensive Care Unit. **The medical director or his/her designee shall be available on-call 24 hours a day.**	Language adds requirement for management coverage 24 hours a day.
(b) A board certified or eligible neonatologist shall be available on call on a 24 hours a day	(b) A board certified or eligible neonatologist shall be available ~~on call~~ **in-**	Enhanced standard for neonatology coverage

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basis. Each NICU shall have a policy describing care situations when the neonatologist's presence is required.	**house** on a 24 hours a day basis. ~~Each NICU shall have a policy describing care situations when the neonatologist's presence is required~~.	support the goal of ensuring a high quality of care for service providing care to high-risk newborns requiring intensive care.
(c) A pediatrician-in-training who has completed the second year of post-graduate residency shall be present in-house and immediately available to the unit, on a 24 hours a day basis.		
(d) The nurse who has responsibility and accountability for the 24 hours a day nursing management of the neonatal intensive care service shall, at a minimum, be baccalaureate-prepared and have additional education in the neonatology specialty area. She or he shall have at least three years of clinical experience, two of which are in the specialty area, and, in addition, meet the qualifications for the position as defined by hospital policy.	(d) ~~The~~ **A** nurse**, designated by the hospital,** ~~who has responsibility and accountability~~ **shall be responsible** for the 24 hours a day nursing management of the neonatal intensive care service. ~~shall,~~ At a minimum, **this nurse shall** be ~~baccalaureate~~**masters-**prepared and have **experience and advanced education in caring for sick newborns.** ~~additional education in the neonatology specialty area~~. She or he shall have at least ~~three~~ **five** years of clinical experience, two of which are in the specialty area, and, in addition, meet the qualifications for the position as defined by hospital policy**. (*****the requirement for a masters degree may be waived for individuals holding this position at the time of the promulgation of the regulation.)*** **A freestanding pediatric hospital with a neonatology subspecialty shall meet the requirements for a nurse educator stipulated in 130.650 (A) (1) (d)**	Enhanced standard for nurse education and experience supports the goal of ensuring a high quality of care for service providing care to high-risk newborns requiring intensive care.
(e) A masters-prepared social worker with a background in maternal-child health shall be available to provide services to this unit.	~~A masters-prepared social worker with a background in maternal-child health shall be available to provide services to this unit.~~ **A masters-prepared licensed social worker with experience in assessment of perinatal patients (mother /infant dyad), education, discharge planning, community follow-up programs, referrals and home care arrangements shall be available as needed to meet patient needs.**	Enhanced standard for social work experience supports the goal of ensuring a high quality of care for service providing care to high- risk mothers and newborns.
(f) A registered dietician with experience in neonatal nutrition shall be available.	(f) A ~~registered~~ dietician **registered by the American Dietetics Association who has expertise in** ~~with experience~~ in ~~neonatal nutrition shall be available~~**. both normal and high risk maternal-newborn nutritional needs and with access to neonatal nutritional resources shall**	Enhanced standard for nutritional services supports the goal of ensuring a high quality of care for hospital providing care to high-risk mothers and newborns seven days a week.

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	be available 7 days a week.	
(g) A respiratory therapist trained in the neonatology specialty area shall be available to the unit on a 24 hours a day basis.		
(h) A medical engineer shall be responsible for the maintenance and safe functioning of specialized equipment per written policy.		
	(i) An IBCLC lactation consultant or individual with equivalent training and experience shall be available 7 days a week. Lactation consultants shall have training and experience in providing care and services to infants with special needs and their families.	Enhanced standard for lactation services supports the goal of ensuring a high quality of care for hospital providing care to high-risk mothers and newborns 7days a week.
(2) Services. The Level III Neonatal Intensive Care Unit shall provide the following:	(2) Services The Neonatal Intensive Care Unit shall be located within either a ~~Perinatal Center~~ **hospital with a Level III Maternal and Newborn Service or** ~~facility with a Level III pediatric service~~ **a Freestanding Pediatric Hospital with Neonatal Subspecialty Services.** The Level III Neonatal Intensive Care Unit shall provide the following	
(a) Emergency transport team for transferring sick newborns from the birth hospital to the neonatal intensive care unit.	(a) **Access to e**mergency transport team for transferring sick newborns from the birth hospital to the neonatal intensive care unit.	Clarification to provide for situations when transport team provided through arrangement with another Level III neonatal service.
(b) Ventilatory assistance and/or complex respiratory management.	(b) Ventilatory assistance and/or complex respiratory management, **including high-frequency ventilation.**	
(c) Capability of continuous intravenous administration of vasopressor agents.		
(d) Insertion and maintenance of all types of venous and arterial lines.	.	
	(d 1) Nitric oxide therapy	Addition of current therapy
(e) Phototherapy.		
(f) Exchange transfusions.		
(g) Continuous cardio-respiratory monitoring.	(g) Continuous cardio-respiratory monitoring **including oxygen saturation monitoring.**	Updated to reflect current standards for equipment availability needed.
(h) Complex nutritional and metabolic management including total parenteral nutrition.		

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(i) Extensive pediatric radiology and subspecialty services.	(i) ~~Extensive~~ **Full range of emergency** pediatric radiology and subspecialty services **available on a 24 hours a day basis.**	Updated to reflect current standards for service availability needed to support Level III care.
(j) Full range of laboratory services including microchemistry available on a 24 hours a day basis.	(j) Full range of laboratory services including microchemistry **and full service blood bank** available on a 24 hours a day basis.	Updated to reflect current standards for service availability needed to support Level III care.
(k) Surgical interventions in the neonate (or written agreements with other institutions providing subspecialty surgical procedures).	(k) **Access to emergency** Surgical interventions in the neonate (or written agreements with other institutions providing subspecialty surgical procedures) **available 24 hours a day.**	Updated to reflect current standards for service availability needed to support Level III care.
(l) Post-surgical care.		
(m) Access to pediatric subspecialty consultation and services including pediatric surgery, neurology, cardiology, gastroenterology, infectious disease, hematology and genetics.	(m) Access to pediatric subspecialty consultation and services including ~~pediatric~~ surgery, neurology, cardiology, gastroenterology, infectious disease, hematology and genetics **available 24 hours a day.**	
(n) Where indicated, a developmental plan including, but not limited to tactile, kinesthetic, auditory and visual measures such as rocking, touching, and vocalization to support positive and reciprocal interaction between infant and parents. (Attention shall also be given to elimination of negative or extraneous environmental stimuli.)	(n) Where indicated, a developmental plan including, but not limited to tactile, kinesthetic, auditory and visual measures such as rocking, touching, and vocalization to support positive and reciprocal interaction between infant and parents. (Attention shall also be given to elimination of negative or extraneous environmental stimuli. a**nd to pain management and monitoring**)	Updated
(o) Availability of developmental consultation.	(o) Availability of developmental consultation, **including occupational and physical therapies.**	Examples added for clarification.
(p) Continuous involvement of parents in infant's care and opportunity for mothers to room-in for pre-discharge education in caring for the infant.		
(q) Crisis-oriented support and ongoing psychosocial services including social work service and the availability of psychiatric consultation for the parents. (Provision for parent support group is recommended.)		
(r) Ongoing written discharge planning.		
(s) Transport capabilities to return patients to Level I and II units.		
(t) Ethics committee for review of complex patient care issues with focus on parental involvement in decision making.		
(u) Professional education.	(u) Professional education **program**.	Clarification language

CURRENT REGULATION	PROPOSED CHANGES	RATIONALE FOR CHANGE
(v) Educational offerings to collaborating community hospitals.	(v) **Availability of** educational offerings to collaborating community hospitals.	
	(w) Parent education appropriate to meet the needs of the infant and family. **(x) Breastfeeding support**	Updated to reflect current standards for service availability needed to support Level III care.
(3) Policies and Procedures. The neonatal intensive care unit shall have written policies and procedures for the following:		
(a) Nursing orientation and ongoing education in theory and skills required to function in the NICU.		
(b) Admission, transfer and discharge of patients.		
(c) Emergency transport of infants from collaborating hospitals. These policies shall require the presence of a physician or neonatology specialty-trained nurse on the transport team and access to telephone consultation with a neonatologist.		Qualifications of nurse clarified.
(d) Research on infants.		
(e) Membership and functioning of the ethics committee.		
(f) If therapeutic formulas are made on-site, policies for preparation and sealing of containers to prevent tampering.		
	(g) **Newborn pain management**	Addition to reflect current standards of care of newborn.
(g) Other policies and procedures as determined by the hospital perinatal committee or the multidisciplinary neonatal intensive care committee.		
(4) Records. In addition to meeting the requirements for records contained in 105 CMR 130.627(B), the newborn's record shall also contain documentation of the following:		
(a) Diagnostic and treatment modalities.		
(b) Family-infant interactions.		
(c) Psychosocial evaluation.		
(d) Staff-parent communication and parental response to the infant's condition.		
(e) Parent education and involvement in both normal and specialized care-giving.		

CURRENT REGULATION	PROPOSED CHANGES	RATIONALE FOR CHANGE
(f) The process used to make decisions where ethical questions are raised, including parental involvement in the process.		
(g) Application of research protocols in the care of the infant.		
(h) Where need identified, a plan for and patient response to positive infant stimulation program.		
(i) Written discharge plans with referrals to community agencies such as parent support groups, visiting nurse associations and early intervention programs.		
(5) Environment. The Neonatal Intensive Care Unit shall meet the following requirements:		
(a) Sleeping space shall be provided for parents who spend extended periods of time with the infant.		
(b) A consultation/demonstration room for private discussions shall be located convenient to the neonatal intensive care unit.		
(c) A separate formula preparation area shall be provided when therapeutic formulas are made on-site. The preparation area shall have a work counter, sink for handwashing and storage facility.		
	(d) **Availability of breastfeeding pump room**	Addition to support breastfeeding
(6) Equipment. The Neonatal Intensive Care Unit shall contain at least the following equipment:		
(a) Incubators.	(a) ~~Incubators~~. Isolettes	Updated language
(b) Cardio-respiratory monitors with high/low alarm.		
(c) Warming tables.		
(d) Infusion pumps.		
(e) Oxygen humidification and warming system.		
(f) Oxygen analyzer.		
(g) Percutaneous oxygen monitor.		
(h) Arterial and venous catherterization equipment.		
(i) Resuscitation and other life support medications and equipment.	(i) Neonatal Resuscitation ~~and other life support~~ medications and equipment **as described by the most current version of the American Academy of Pediatrics Neonatal Resuscitation Program guidelines**.	Updated
(j) Ventilators with heated humidity and alarm systems. (The respiratory therapist shall check		

CURRENT REGULATION	PROPOSED CHANGES	RATIONALE FOR CHANGE
machine settings and functioning regularly per departmental policy.)		
(k) Transducers for invasive cardiac monitoring.		
(l) Immediate accessibility to microchemistry laboratory.		
(m) Transport isolette(s).		
	(n) Electric breast pump(s)	Addition to support breastfeeding
	(o) Separate nutrition support area	Addition to support delivery of adequate nutritional care
130.660: Minimum Lengths of Stay		
The minimum length of inpatient stay for mothers and infants shall be 48 hours following a vaginal delivery and 96 hours following a cesarean section. These time periods begin at the time of the infant's birth. Inpatient stays of less than these time frames shall constitute early discharge. No discharge shall occur between the hours of 8:00 P.M. and 8:00 A.M. without the mother's agreement. Any decision to shorten these minimum stays shall be made by the attending practitioners for both mother and infant in consultation with and upon agreement by the mother. For the purposes of 105 CMR 130.660, attending practitioner shall include obstetrician, pediatrician, family physician, or otherwise qualified attending physician, certified nurse midwife, or nurse practitioner.		
130 .661: Early Discharge Protocols		
Each hospital operating a maternal-newborn service shall develop protocols governing early discharge for mothers and infants. Protocols shall be developed in collaboration with obstetric, pediatric and nursing practitioners, and shall be consistent with guidelines and early discharge criteria set forth by the American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Pediatrics (AAP) and at a minimum shall provide that early discharge may be considered only when the simultaneous discharge of the mother and infant is feasible and		
only after environmental and other risk factors affecting the well-being of the mother and infant have been assessed. Nothing in 105 CMR 130.661 shall affect the right of a mother to		

CURRENT REGULATION	PROPOSED CHANGES	RATIONALE FOR CHANGE
voluntarily choose an early discharge.		
130.662: Notices		
Mothers shall be informed in writing, at the time of admission and with any pre registration materials, in language understandable to the mother and in their own language, by the hospital, payors or insurers subject to the provisions of St. 1995, c. 218, of their rights under 105 CMR 130.660 through 130.669. The notice shall include, but not be limited to, information about the minimum lengths of inpatient stay of 48 hours following a vaginal delivery and 96 hours following a cesarean section; the right to home visits as provided for in 105 CMR 130.665 following early discharge; and the process and telephone number for filing appeals, if they feel their rights have been violated. Model language for implementation of 105 CMR 130.662 will be provided by the Department.		
130.663: Discharge Plans		
The hospital shall develop a comprehensive written discharge plan for each mother and newborn for whom an early discharge is contemplated. Said discharge plan, at a minimum, shall identify the mother's and newborn's primary health care providers and specify and arrange for existing, appropriate home care services consistent with ACOG and AAP early discharge guidelines.		
130.664: Transfer of Clinical Information		
Each hospital operating a maternal-newborn service shall develop protocols for the transfer of pertinent clinical information concerning the mother and infant to the professional or agency providing the home care services. A minimum standard for content should include specific information on the timing and necessity of performing newborn screening as well as information regarding relevant prenatal, birth and hospital postpartum course of care.		

CURRENT REGULATION	PROPOSED CHANGES	RATIONALE FOR CHANGE
130.665: Home Visits		
Eligible mothers and infants who participate in early discharge shall be provided, upon agreement by the mother, a minimum of one home visit. The first home visit shall occur within 48 hours following discharge of the mother and infant and shall be conducted by a registered nurse, physician, or certified nurse midwife trained in maternal and infant care. Any subsequent visits determined to be clinically necessary shall be provided by a licensed health care professional or appropriately trained individual under the supervision of a licensed health care professional. Subsequent home visits for the mother and infant shall be based on need as determined by the attending practitioners in consultation with the mother. Minimum content of the first home visit includes review of relevant health history, physical examination of the mother and infant, performance of newborn screening tests, assessment/teaching of maternal self care, infant care, breast/bottle feeding, and the need for social support communication with primary obstetric and pediatric health providers and referral to appropriate follow-up resources. Refusal of any services as specified in 105 CMR 130.665 shall be documented.		
130.666: Appeals		
Denial of benefits under St. 1995, c. 218 may be appealed to the Department of Public Health. Appeals may be filed by contacting the Department by telephone. The Department shall establish a toll-free telephone number to receive such appeals.		
130.667: Notification and Request for Information		
Upon receipt of the appeal, the Department shall immediately contact the hospital, post hospital provider, payors or insurers subject to the provisions of St. 1995, c. 218 as appropriate, and may require that portions of the patient's record be immediately furnished to the Department.		
130.668: Appeal Decision		

CURRENT REGULATION	PROPOSED CHANGES	RATIONALE FOR CHANGE
Upon review of all relevant information, the Department shall make a determination regarding whether the mother or infant has been denied benefits pursuant to 105 CMR 130.660 through 130.669. Such decision shall be communicated to the patient and to the hospital, post hospital provider, payors or insurers subject to the provisions of St. 1995, c. 218, by telephone immediately following the receipt of all requested information. The Department shall send written confirmation of its decision within a reasonable period of time.		
130.669: Stay Pending Appeal		
The filing of an appeal shall stay any proposed early discharge of the mother and the infant during the pendency of the appeal.		